EXHIBIT B

Filed with Redactions

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	§ § § §	MDL NO. 2875 HONORABLE ROBERT B. KUGLER DISTRICT COURT JUDGE

ORAL AND VIDEOTAPED DEPOSITION OF
JOHN L. QUICK
JANUARY 27, 2022

ORAL AND VIDEOTAPED DEPOSITION OF JOHN L. QUICK, produced as a witness at the instance of the Defendants and duly sworn, was taken in the above styled and numbered cause on Thursday, January 27, 2022, from 9:33 a.m. to 7:00 p.m., before TAMARA CHAPMAN, CSR, RPR-CRR in and for the State of Texas, reported by computerized stenotype machine, at the offices of Slack Davis Sanger, LLP, 6001 Bold Ruler Way, Suite 100, Austin, Texas, pursuant to the Federal Rules of Civil Procedure and any provisions stated on the record herein.

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I N D E X

E X H I B I T S

E X H I B I T S
(Continued)

E X H I B I T S
(Continued)

THE VIDEOGRAPHER: Here begins the deposition of John Quick. Today's date is January 27th, 2022. The time is 9:33 a.m.

Will the court reporter please swear in the witness?

THE REPORTER: And will you introduce yourselves for the record?

MS. ISIDRO: Nilda Isidro from Greenberg Traurig on behalf of defendant, Teva.

MR. KERNER: I'm Glenn Kerner from Greenberg Traurig, also on behalf of Teva.

MR. DAVIS: John Davis, Slack Davis Sanger, on behalf of the plaintiffs.

MS. HILTON: Layne Hilton, Kanner & Whiteley on behalf of the plaintiffs.

MS. WHITELEY: Conlee Whiteley, Kanner & Whiteley, on behalf of plaintiffs.

JOHN L. QUICK,

having been first duly sworn, testified as follows:

EXAMINATION

BY MS. ISIDRO:

Q. Good morning, Mr. Quick.

A. Good morning.

Q. My name is Nilda Isidro. I am from the law firm of Greenberg Traurig and I represent

defendant, Teva. We're meeting for the first time this morning. Correct?

A. That's correct.

Q. I'm going to be asking you some questions today. And if we could start, could you please state your full name for the record.

A. John Lowell Quick.

Q. What is your current professional address?

A. W1800 County Road B, Genoa City, Wisconsin 53128.

Q. Thank you. Mr. Quick, you've been deposed before. Correct?

A. I have.

Q. So you know how this goes, but I'm just going to go over a few ground rules before we get started.

As you know, there is a court reporter to your left taking down everything that anyone in the room says. For that reason it's very important that you answer verbally. So, for example, saying "yes" or "no," rather than nodding your head or saying "uh-huh" or "uh-uh," just so that we can make sure that the written transcript is clear.

It's also important that before you start

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to answer a question, you wait for me to finish getting the question out completely, not anticipate what I'm trying to ask. And this is, again, just so that the court reporter isn't trying to take both of us down talking at the same time.

If at any time you don't understand my question or you don't hear me, please let me know. I'm happy to repeat it or to clarify whatever might be confusing about the question. But if you do answer my question, I'm going to assume that you understood it. Fair enough?

A. Fair.

Q. All right. If you need a break at any time, please let me know. I would just ask that if there is a question pending, we get the question answered first and then we can take a break.

Do you have any questions at all -- oh, one more thing. In addition to the folks in the room, we have some folks on Zoom. So, for example, when we're dealing with exhibits, there may be a little bit of a pause as we wait for the exhibit to get up on the Zoom as well. And there may be folks asking questions on the Zoom later on. All right?

Is there any reason, as you sit here today, why you may not be able to give accurate and truthful testimony?

A. No.

Q. You're not on any medications that might impact your ability to give accurate and truthful testimony?

A. No, I'm not.

MS. ISIDRO: And, again, just remember to let me finish my question before you start to answer.

MR. DAVIS: And give me a little time to place an objection, as appropriate, as well. So build even more of a little delay in there. Thanks.

Q. And do you want to read and sign the deposition?

A. I'm sorry?

MR. DAVIS: We can handle that at the end, Nilda.

MS. ISIDRO: Okay. Sure.

Q. All right. Mr. Quick, have you ever been a party to a lawsuit?

A. Maybe you can rephrase. I'm not sure.

Q. Sure. Have you ever been the plaintiff or the defendant in a lawsuit?

A. No.

Q. Have you -- aside from this litigation, have you ever been retained as an expert witness?

A. Yes.

Q. On how many occasions have you been retained as an expert witness?

A. Multiple occasions.

Q. Can you approximate a number?

A. Approximately five. It could be more or less.

Q. Fewer than ten?

A. Fewer than ten.

Q. Okay. And have you ever testified, prior to today, at a deposition as an expert witness?

A. Yes.

Q. On how many occasions?

A. Probably the same number.

Q. So there haven't been any cases where you were retained where you did not testify at deposition?

A. I don't believe so.

Q. Okay. Have you ever testified at a deposition other than as an expert witness?

A. Yes.

Q. On how many occasions?

A. 10, 15 times maybe.

Q. When was the last time that you testified at a deposition not as an expert witness?

A. I'm not certain, but maybe 15 years ago.

Q. And what was the -- what was the context for your being deposed at that time?

A. Probably that -- I'm not certain the time frames, but at that time it may have been related to a situation at Baxter, my former employee, when they asked me to testify on a situation that had occurred when I was in an employ at the company.

Q. So for the 10 to 15 times that you testified not as an expert witness, did those all relate to your employment at Baxter?

A. No.

Q. Okay. About how many of them related to your employment at Baxter?

A. Probably all of them, but maybe two or three.

Q. And what did those two or three that were not related to Baxter relate to?

A. We're going a long ways back. One related to a situation with a contract manufacturer in California. One related to a medical device company. Those are the two I can recall.

Q. And so in the matter involving the contract manufacturer in California, what was the

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reason for you being deposed?
A. The issue related to a -- one of their customers. It was a contract dispute and the issue related to whether they fulfilled their contract. And so I was brought in as an expert on Q7 relative to APIs.
Q. Okay. So that was one of the instances where you were deposed as an expert witness?
A. Yes.
Q. Okay. So focusing only on the times where you were deposed not as an expert witness, you said there were about 10 to 15 of those.
Is that right?
A. No.
Q. Okay.
A. I said there were probably three or four. Again, we're really stretching my memory. Some of these go back years.
Q. Okay. I want to make sure I understood because what I had understood from your testimony was that you had been deposed approximately five times as an expert witness and then approximately 10 to 15 times not as an expert witness.
A. Okay. That's probably right.
Q. So were you ever deposed as a fact

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witness, so not as an expert, in connection with anything other than your employment at Baxter?
A. I don't believe so. I would qualify that these were not characterized the way you're characterizing them, at the time.
Q. Okay. How were they -- how were they characterized?
A. I'm saying they were not characterized at all.
Q. Am I understanding that you didn't necessarily know whether you were testifying as an expert witness or as a fact witness?
A. Well, to differentiate --
THE WITNESS: I'm sorry.
MR. DAVIS: I'm going to object for the record. You can answer the question.
A. The differentiation wasn't made at the time.
Q. Okay. So let me ask it this way.
When you're testifying as an expert witness, is it always the case that you are retained as an expert in that matter?
A. Going back all those years, I honestly don't know how I was retained. In some cases I was actually working for the group where I was acting as

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an expert witness.
Q. And would that have been in connection with Baxter or something else?
A. Something else.
Q. And what was that?
A. So the one I indicated was a medical device company. One was a contract manufacturer in California. There was another one that -- back in the 2012 time frame, where I was an expert witness for a private equity company. They were doing battle with another private equity company over an escrow. And so I was an expert witness. And that situation related to sterile aseptic processing.
Q. Okay. And in those instances the company on whose behalf you were testifying was your employer?
MR. DAVIS: Objection to the use of the word "employer."
A. I wasn't an employer. I was a consultant. I was retained as a consultant.
Q. Okay. But you were retained?
A. Right.
Q. When you're testifying as an expert or as a consultant, you're compensated. Correct?
A. That's correct.

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Q. Have you ever provided deposition testimony for which you were not compensated?
A. I've had -- I've been at -- well, for example, the Baxter deposition I referred to back 10, 15 years ago, I was not compensated for that. It wasn't explained I was an expert witness. I was just called to testify. I was not compensated for that.
Q. And what did that lawsuit involve, in general terms?
A. It related to a labeling issue with a -- one of the products that Baxter had. And it goes back to the early '90s.
Q. And you were deposed when in connection with that case?
A. Yes.
Q. My question was you were deposed when in connection with that case?
A. Oh. I'm saying it was probably about 15 years ago. It was long after I left Baxter.
Q. Okay. Have you ever testified at trial as an expert witness?
A. Yes.
Q. On how many occasions?
A. Once.

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Q. And what case was that?
A. This was the case on the aseptic processing issues where the two private equity groups were disputing the escrow amount.
Q. When did that trial take place?
A. I believe it was somewhere in the 20 -- 2012 time frame. If we need an exact date, I can get an exact date.
Q. What were -- what were the names of the parties in that lawsuit?
A. I don't recall offhand, but I can certainly get that if we need that.
Q. Okay.
A. It's been a long time. It's been ten years.
Q. Do you remember the name of the private equity firm?
A. I don't offhand.
Q. Okay. To your knowledge, have you ever had your opinions excluded or limited by any court?
A. Not that I'm aware of.
Q. So we talked about at least two instances where you were retained as a consultant. That's the contract manufacturer issue in California and the medical device company issue. Correct?

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A. That's correct. Just to clarify, though, I've obviously been retained as a consultant for many other situations where I was not testifying as an expert witness.
Q. Okay. So these are the two that you recall --
A. Right.
Q. -- where you did testify where you were being retained as a consultant but you also testified as an expert witness. Correct?
A. Correct.
Q. And you also mentioned there were about five instances where you have been retained as an expert and testified as an expert at a deposition. Correct?
A. Correct.
Q. Okay. What was the last time, the most recent time, that you testified as a retained expert witness at a deposition?
A. Two -- almost exactly two years ago.
Q. What was that case?
A. This was the hernia mesh case.
Q. Were you testifying on behalf of the plaintiff in that case?
A. Yes.

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Q. And prior to that, when was the last time that you testified as an expert witness?
A. Probably the situation I referred to back in 2012.
Q. Okay. That was the contract manufacturer issue?
A. This was the two private equity groups.
Q. Two private equity groups.
A. Again, these were -- I'm trying to recall from memory for long periods of time in the past.
MR. DAVIS: And I just caution you not to speculate. If you don't remember something, you don't remember it, but...
Q. So prior to the case with the two private equity groups, when was the last time before that that you testified as an expert witness?
A. The two cases that I referenced, one was the medical device company and one was the contract manufacturer. I'm not sure which was first, which was last.
Q. And the case with the contract manufacturer in California that one was approximately when?
A. It was approximately 15 years ago.
Q. And how about the one with the medical

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device company?
A. It was somewhere in the same time frame.
Q. Do you recall providing testimony as an expert witness at any time prior to that?
A. I don't believe so, but I'm not certain.
Q. In the matter involving the two private equity groups, were you testifying on behalf of the plaintiff or the defendant?
A. That's a good question. I'm not sure which was which.
Q. And in the matter involving the contract manufacturer in California, were you testifying on behalf of the plaintiff or the defendant?
A. Probably the defendant in that case.
MR. DAVIS: I'd caution you not to speculate. If you know, you know --
A. I'm --
MR. DAVIS: -- if you don't, you don't.
A. -- I'm not certain who was suing who there, but...
Q. Okay. And in the matter involving the medical device company, were you testifying on behalf of the plaintiff or the defendant?
A. Again, I'm -- I'm not certain.

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Q. Are you listed in any databases of experts?
A. I'm sorry?
Q. Are you listed in any databases of experts?
A. Not that I'm aware of.
Q. Have you ever advertised for your services as an expert?
A. No.
Q. Have you ever spoken or given a presentation to a group of lawyers?
MR. DAVIS: Objection; vague.
But you can answer.
A. Maybe you want to clarify that a little.
Q. What do you need clarification on?
A. Well, I don't know. You said a group of lawyers. I mean, I -- I deal with lawyers all the time.
Q. So other than in a matter where you've been engaged as an expert, have you ever given a presentation to a group of lawyers?
MR. DAVIS: Same objection.
You can answer.
A. Like I said, I deal with lawyers all the time and so when you say "a presentation to a group

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of lawyers," it's not very clear what you're trying to ask.
Q. So -- so is that a "yes" --
A. I don't know.
Q. -- you have given a presentation to a group of lawyers? I mean, you said you deal with lawyers all the time.
A. So I -- so when you're saying a presentation, so I deal with lawyers all the time. And so when you're asking about giving a presentation, I mean, I've had interactions with groups of lawyers. I'm -- I'm not really sure where you're going with this, so I'm not sure how to answer your question.
Q. In what context do you deal with lawyers all the time?
A. So I -- I, again -- I'm involved very heavily in diligence for groups that want to buy another company and lawyers are involved in all of these situations.
Q. And are you -- in those instances, have you been hired as a consultant to provide diligence?
A. Yes.
Q. So other than in a situation where you've been hired as a consultant or hired as an expert,

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have you ever given a presentation to a group of lawyers?
A. Not that I'm aware of.
Q. Have you ever spoken at a legal conference?
A. I did speak years ago at -- actually, I think it's in my CV. I forget the group. We could pull up my CV and we could look. So there was a presentation years ago. I think it was -- I want to believe a group sponsored it. But this has been a long time ago.
Q. All right.
MS. ISIDRO: Why don't we go ahead and mark that CV as Exhibit 1.
(Exhibit 1 was marked.)
MR. DAVIS: Are you going to have a copy for me, Nilda?
MS. ISIDRO: Yes, I am. Just bear with me as I'm actually marking the exhibit.
MR. DAVIS: Thank you.
Q. Mr. Quick, I've just handed you Exhibit 1. Is that your CV?
A. Yes.
Q. You said you would be able to locate that presentation on your CV. So if you could take a

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look and do that for me, please.
A. (Pause.)
It's the last one on Page 6. This was the FDLI.
Q. I see. July 11, 1995?
A. That's correct.
Q. Okay. That's the only time you've ever spoken at a legal conference?
A. I -- I believe that to be the case.
Q. Are you affiliated with any expert witness services?
A. No.
(Discussion off the written record.)
MS. ISIDRO: Why don't we go off the record for a minute and take care of the issue.
THE VIDEOGRAPHER: Off the record at 9:56 a.m.
(Break.)
THE VIDEOGRAPHER: Back on the record at 10:02 a.m.
Q. Mr. Quick, have you ever done consulting work for a pharmaceutical company?
A. Yes.
Q. How many times?
A. I don't have a number.

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Q. More than ten?
A. More than ten.
Q. More than 20?
A. Probably. I -- I really don't know.
Q. In what context have you provided consulting to pharmaceutical companies?
A. Primarily as it relates to quality and regulatory and/or diligence.
Q. Have you ever provided consulting services to any of the defendants in this litigation?
A. Yes.
Q. Which ones?
A. Mylan.
Q. When was that?
A. I put the dates -- I think the dates are in the -- in the report. If I had the report, I could give you the exact dates.
Q. Other than Mylan, have you ever provided consulting services for any defendant in this litigation?
A. No.
Q. And you've never provided consulting services for Teva. Correct?
A. No, I've not, although I've been to Teva

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facilities as part of another situation.
Q. And what situation was that?
A. Diligence.
Q. So you were providing diligence for another entity regarding Teva?
A. That's correct.
Q. And that's disclosed in your report as well. Correct?
A. Correct.
Q. What percentage of your income is generated through legal consulting?
A. Would you repeat that, please?
Q. What percentage of your income is generated through legal consulting?
MR. DAVIS: I'm going to -- before he answers that, I'm going to object to that as vague.
A. It's a -- it's a very complicated situation. All my consulting is done through Quick & Associates. I receive no salary as a result of working for Quick & Associates. I have a pension from Baxter International, which is where my income is. There's -- it's -- if we want to spend the time, I could get into the specifics as to how our finances are handled.
Q. What percentage of your time at Quick &

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Associates is spent on consulting in connection with legal matters, lawsuits?
A. Legal matters?
Q. Uh-huh.
A. Would you want to define what you mean when you say "legal matters"?
Q. I said "lawsuits."
A. A low percentage.
Q. 25 percent?
A. Probably less than that.
Q. 10 percent?
A. Probably less than that. I don't have a number.
Q. Are you currently consulting in connection with any litigation, other than this one?
A. Not that I'm aware of.
Q. You would be aware of matters that you are currently consulting on. Correct?
A. I am aware. I do a lot of consulting for a lot of different entities. There's -- there's no specific litigation that I'm aware of for any of those.
Q. How much money did you make last year from serving as an expert witness?
A. I don't have that number.

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Q. How much money have you made so far this year from serving as an expert witness?
A. I've received nothing this year as a result of serving as an expert witness.
Q. Have you billed for any services rendered as an expert witness over the course of this year so far?
A. In 2020? No.
Q. In 2022?
A. 2022, no.
Q. In 2021, did you provide any consulting or expert witness services in connection with any litigation, other than this one?
A. I don't believe so.
Q. How much are you charging per hour for your work in this case?
A. $400 per hour for consulting, $500 for depositions, and any trial work.
Q. And is that $500 flat per hour for depositions?
A. What do you mean, "flat"?
Q. 500, not 540 or --
A. $500, yes.
Q. $500.
A. I believe that's in the report as well.

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Q. How do you track the time that you spend on this litigation?
A. How do I track?
Q. Uh-huh.
A. I track all of my time. I've got a internal spreadsheet system that I use, so I -- that's how I track it.
Q. So you have records of all of the time that you have spent on this matter. Correct?
A. I do.
Q. And that includes your time spent during calendar year 2022?
A. Yes.
Q. How often do you generate invoices in connection with your work on this litigation?
A. There is no predetermined frequency.
Q. So how do you determine at any given point when to issue an invoice?
A. It's usually after some significant work has occurred. There is no set time frame.
(Exhibit 2 was marked.)
Q. All right. And we've marked as Exhibit 2 a document that has "Consulting Agreement" as the title. I'm handing it to you right now. Please take a look at that.

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A. (Pause.)
Q. Is that your consulting agreement in connection with this litigation?
A. It is.
Q. And if you turn to the second page, there is a heading for "Compensation." Correct?
A. Correct.
Q. And that first section, 3.1, states that: Compensation will be at the rate of $400 per hour for consulting work.
That's -- you mentioned previously. Correct?
A. Correct.
Q. And it also says: There is an alternative fee of $3,200 per day, regardless of the number of hours in the day exceeding eight hours?
A. Correct.
Q. Have there been any instances in this litigation where you have used that 3,200 per day in a given day?
A. I don't believe so, but, I -- I'd have to go back and check.
Q. And continuing in that section, it says that: For expert testimony work, i.e., trial testimony or deposition testimony, the rate will be

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at $525 per hour.
A. I see that.
Q. Is that correct?
A. That is correct, and what I said earlier was incorrect.
Q. Okay. So your hourly rate for testimony, including here today, is 525 an hour?
A. That's correct.
Q. And it also says that there is an alternative fee of 4,200 -- $4,200 per day, regardless of the number of hours in the day exceeding eight hours?
A. That's correct.
Q. Does that apply for purposes of your deposition at your deposition here today?
A. Yes.
MR. DAVIS: Assuming we exceed eight hours.
Q. But there is no reason that that provision would not apply with respect to a day of deposition testimony, including today, if we exceed eight hours?
A. That's correct.
Q. I'm going to mark some invoices as the next few exhibits. Just bear with us a moment. You

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know what, I'm going to do this as a composite exhibit so we just mark a single exhibit. Just bear with me.
(Exhibit 3 was marked.)
MR. DAVIS: Are you going to order them in chronological order, Nilda?
MS. ISIDRO: Sure, we can do that.
Q. Okay. So I'm handing you what's been marked as Exhibit 3. Can you confirm for me that it contains seven pages of invoices?
A. (Pause.)
Yes.
Q. Great.
And the first invoice that's there is an invoice from July 2nd, 2020. Correct?
A. Correct.
Q. That's Invoice QA973?
A. Correct.
Q. And that invoice is for a total of $12,400. Correct?
A. Correct.
Q. And have you been paid on that invoice?
A. Yes.
Q. The full amount?
A. Yes.

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Q. Okay. And the next invoice is Invoice QA974 dated July 11th, 2020.
A. (Pause.)
Q. Is that right?
A. That's right.
Q. And that invoice is for a total of $11,200. Correct?
A. That's correct.
Q. Were you paid on that invoice?
A. I was.
Q. The full amount?
A. The full amount.
Q. Okay. The next invoice is Invoice QA983. Is that right?
A. That's correct.
Q. Dated October 4th, 2020?
A. That's correct.
Q. For a total amount of $19,600?
A. That's correct.
Q. Were you paid on that invoice?
A. I was.
Q. The full amount?
A. The full amount.
Q. The next invoice is Invoice No. QA990. Is that right?

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A. Yes.
Q. Dated December 5th, 2020. Correct?
A. Yes.
Q. For a total amount of $15,600?
A. Yes.
Q. Were you paid on that invoice?
A. I was.
Q. Were you paid the full amount?
A. Yes.
Q. The next one is Invoice QA1003. Is that right?
A. That's correct.
Q. Dated May 2nd, 2021?
A. Yes.
Q. For a total amount of $16,400?
A. Yes.
Q. Were you paid on that invoice?
A. I was.
Q. Were you paid the full amount?
A. I was.
Q. The next one is Invoice QA1016, dated July 18, 2021. Is that right?
A. That's correct.
Q. For a total amount of $4,400?
A. Yes.

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Q. Were you paid on that invoice?
A. I was.
Q. And were you paid the full amount?
A. I was.
Q. And the last invoice in Exhibit 3 is Invoice QA1034, dated November 7th, 2021. Is that right?
A. That's right.
Q. And that's for $44,000. Correct?
A. Correct.
Q. Were you paid on that invoice?
A. I was.
Q. Were you paid the full amount?
A. I was.
Q. Have you issued any invoices since that November 7th, 2021, invoice?
A. I don't believe so.
Q. And have you issued any invoices, other than the seven invoices that we have here in Exhibit 3?
A. Not that I'm aware of.
Q. These invoices are addressed to Plaintiffs' Steering Committee. Correct?
A. That's correct.
Q. Who do you actually send your invoices to

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when you generate them?
A. I send these to Rosemarie Bogdan.
Q. And that's true for all of the invoices?
A. That's -- yes.
Q. Okay. Following this November 7th, 2021, invoice, have you spent time on this litigation?
A. Yes.
Q. How much time?
A. I don't know. I'd have to go back and check my records. I really don't know. If we -- if that's important, we could get that number.
Q. Okay. And after today, do you intend to continue spending time on this litigation?
MR. DAVIS: Objection; calls for speculation, I suppose.
A. It's -- it's -- I don't know, unless -- if I'm asked to, I probably would do so.
Q. Is it --
A. I haven't been asked, but I've -- if I was, I probably would do so.
Q. Is it your understanding -- is it your understanding that your services will be ongoing during the pendency of the litigation?
MR. DAVIS: Objection.
You can answer.

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A. We've had no concrete discussion that's going to happen. I'm assuming it probably would, but...
Q. And so looking at these invoices, these seven invoices that are in Exhibit 3, through November 7th of 2021, you've been paid $123,600 for your work in connection with this litigation?
A. I haven't added them up, but if that's the number when they add up, that would be correct.
Q. Who first contacted you in connection with this litigation?
A. Rosemarie.
Q. And did you know Rosemarie before she contacted you in connection with this litigation?
A. No, I did not.
Q. Did you have a relationship with any of the plaintiffs' counsel or their firms prior to this -- prior to being engaged to work on this litigation?
A. No.
THE WITNESS: I'm sorry.
MR. DAVIS: Just give me a little time to place an objection.
THE WITNESS: Okay.
MR. DAVIS: So I'm going to object to

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that as vague.
Q. When were you first contacted in connection with this litigation?
A. I don't have a date.
Q. It would have been before July 2nd of 2020. Correct?
A. That's correct.
Q. And, in fact, it would have been before May 28th of 2020, which is the first date reflected on that July 2nd, 2020, invoice. Correct?
A. That would be correct.
Q. What were you asked to do when you were contacted about this litigation?
MR. DAVIS: I'm going to object.
But you can answer for now.
And I think the assignment he was given is reflected in his declaration, but feel free to answer.
A. I was asked to -- again, we're going back probably two years. I was asked to do consulting work in regard to this litigation. I was asked what documents I might need to review in the scope of this, understanding where we were at that time. I provided a list of documents to Rosemarie that I thought I would need in order to do a review.

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Q. Were you provided with everything you asked for?
A. I don't believe so. I don't believe all the documents have yet been provided, but I don't -- I'm not certain. I think most probably have, but I'm not certain.
Q. What did you request that was not provided?
A. I don't know. It was a two-page list and I have not checked off which ones were not provided. I could probably made that determination if we need that information.
Q. You still have a copy of that list?
A. I do.
Q. I'm going to ask you to make sure you preserve a copy of that list.
A. I will.
Q. In connection with your work on this litigation, is there anyone who assists you with research?
A. No.
Q. Have you reviewed the opinions of any of plaintiffs' other experts in connection with this litigation?
A. No, I have not.

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Q. Have you reviewed the opinions of any defendants' experts in connection with this litigation?
A. No, I have not.
Q. Were you provided with any assumptions that you were asked to take as true in connection with forming your litigations -- with forming -- let me repeat that question from the beginning.
Were you provided with any assumptions that you were asked to take as true in forming your opinions in connection with this litigation?
MR. DAVIS: Object to the form.
You can answer.
A. I'm not sure I understand exactly what you're asking. Maybe you want to clarify?
Q. In forming your opinions in connection with this litigation, were there any facts that you assumed to be true and did not independently verify?
A. No, not that I'm aware of.
MR. DAVIS: And same objection to form on that question.
Q. Have you ever communicated with any of the plaintiffs in this litigation?
A. No.
Q. Have you ever communicated with any of

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their medical providers?
A. No, I have not.
Q. In connection with this litigation have you communicated with anyone at any of the defendant companies?
A. No, I have not.
Q. Have you ever reviewed any of plaintiffs' medical records?
A. No, I have not.
MR. DAVIS: We've been going about an hour. Do you want to take a break or...
MS. ISIDRO: Sure. We can take a quick break.
THE VIDEOGRAPHER: Off the record, 10:28 a.m.
(Break.)
THE VIDEOGRAPHER: Back on the record. The time is 10:43 a m.
(Exhibit 4 was marked.)
Q. Mr. Quick, I am handing you Exhibit 4, which is the notice of deposition -- the amended notice of deposition for your deposition today.
Have you seen this before?
A. I have.
Q. And have you seen -- if you turn to

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Page 6, there is a list of requests. Have you seen that before today?
A. I have.
Q. And did you assist in putting together documents responsive to those requests?
A. Yes. I was provided a copy of this. I believe that you have been provided with responses to these.
Q. So you're aware that we received some documents in response to these requests, and some written responses in response to these requests a couple of days ago?
A. I am.
Q. Did you assist in putting those together?
MR. DAVIS: I'll object to the form on that.
You can answer.
A. I believe they provided documents to you that were already available. I didn't do any -- I don't believe I did any special work on this as a result of this. They were already there.
Q. I am marking as Exhibit 5 a document that's titled: Guidance for Industry Presenting Risk Information in Prescription Drug and Medical Device Promotion.

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(Exhibit 5 was marked.)
Q. Are you aware that this is one of the documents that was produced in response to the requests in your amended notice of deposition?
A. There are a lot of documents. I'm not certain about this particular one.
Q. Okay. Is this a document that you reviewed and relied on in forming your opinions in this litigation?
A. If I referenced it in my report or listed in the report, I did. If not, it was not. I'd have to go back and look to verify for certain.
Q. Okay.
MR. DAVIS: And I'll object to compound on that.
Q. All right. Why don't we go ahead and mark your report as the next exhibit, Exhibit No. 6.
And, Mr. Quick, I've just handed you Exhibit No. 6. Is this a copy of your report in this litigation?
(Exhibit 6 was marked.)
A. It is.
Q. And behind the report itself, there is an Exhibit A, is that right, following Page 37 of the report?

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A. There is.
Q. Is that -- and the title of that Exhibit A is: Materials Relied Upon for the Declaration?
A. That's correct.
Q. Is that what you were referencing just a few minutes ago when you said that if -- if Exhibit 5 was listed in your report, then it was something that you relied on?
A. That's correct.
Q. And do you see Exhibit 5 listed within Exhibit A of your report?
A. I don't see it, unless it was one of the links on the websites.
Q. Looking at the links, is it -- is Exhibit 5 among any of those?
A. I don't believe it is.
Q. Okay. So Exhibit 5 is not something that you relied on in forming your opinions in connection with this litigation?
A. Well, the documents I relied on, or the ones that are on the list, are the ones I footnoted.
Q. Right. And Exhibit 5 is not --
A. It doesn't appear to be.
Q. All right. And we are marking as

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Exhibit 7 a document that is titled: M7(R1) Assessment and Control of DNA Reactive (Mutagenetic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk.

(Exhibit 7 was marked.)

Q. Mr. Quick, are you aware that this is one of the documents that was produced to us as responsive to the requests that were attached to your amended notice of deposition?

A. Are you asking if it's on my list?

Q. No. I'm asking if you're aware that it was one of the documents that was produced to us as responsive to the requests that were attached to your amended notice of deposition?

A. I'm not certain.

Q. So you do not know, one way or the other, whether it was included?

MR. DAVIS: I think whether it is included is just a fact. He can answer to whether he's aware of it.

MS. ISIDRO: I'm asking as to what he was aware of.

MR. DAVIS: Okay. Sure. Yeah.

MS. ISIDRO: Right.

A. I don't believe so.

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Q. You don't know one way or the other or you --

A. No, I -- if it's --

MR. DAVIS: I caution you not to speculate.

THE WITNESS: Okay.

A. So I don't know.

Q. Okay. And is Exhibit 7 one of the documents that you reviewed and relied on in forming your opinions in this litigation?

A. No.

MR. DAVIS: Same objection, compound.

Q. Is Exhibit 7 one of the documents that you relied on in forming your opinions in this litigation?

A. No.

Q. And I'll take back Exhibits 5 and 7.

A. Which -- which one you want?

Q. 5 and 7. Thank you.

And I'm going to hand you Exhibit 1 again, your CV. If you can just take a quick look at that and let me know if there are any updates to your CV that are not reflected on Exhibit 1?

MR. DAVIS: I'll object to that as vague.

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A. I'm not sure I understand what you're asking.

Q. Have there been any updates that should be reflected on your CV that are not listed there? Anything more recent, for example?

A. No.

Q. So the CV is complete and accurate as reflected in Exhibit 1?

MR. DAVIS: Object to form.

You can answer.

A. That's correct.

Q. Okay. Turning back to the list of documents that you relied on, Exhibit A to your report?

MR. DAVIS: For the record, that's Exhibit 6.

MS. ISIDRO: Correct. Exhibit A within Exhibit 6 to this deposition.

Q. Are there any new materials that you have reviewed in connection with this litigation since putting together the list that's in front of you in Exhibit A to Exhibit 6?

MR. DAVIS: Object to form.

You can answer.

A. I don't believe so.

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Q. So, as you sit here today, you don't have any updates to that list?

A. Not that I'm aware of.

Q. What did you do to prepare for this deposition?

A. Well, I reread my report. We had discussion yesterday afternoon and we had a call --

MR. DAVIS: And I'll caution you not to reveal the substance of those discussions.

THE WITNESS: Okay.

A. And there was a teleconference.

Q. And when you say "we" had a discussion, who are you referring to?

A. The attorneys in this room.

Q. And that does not include myself. Correct?

A. No, it did not include you. That's correct.

Q. It also doesn't include my colleague, Glenn Kerner. Correct?

A. That's correct.

Q. And when you reference a teleconference, can you please tell me who was on that teleconference? Who participated?

A. The three attorneys on the right side of

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the room and some other folks. I don't recall who else was on the call. We could get that list, but I don't recall.
Q. Do you know whether everyone who was on that call was an attorney for the plaintiffs in this litigation?
A. I believe that to be the case.
Q. To the best of your knowledge, there was no one on that call who was not an attorney for the plaintiffs in this litigation?
A. That's correct.
Q. Other than yourself. Right?
A. Right.
Q. Okay. Turning back to your CV, Exhibit 1. You've been an independent consultant from 2003 to the present?
A. That's correct.
Q. And has that been exclusively through your own company?
A. I'll clarify. There were one or two situations where I was engaged by another consulting firm to work with them, but it was still through my own consulting firm.
Q. And your own consulting firm is Quick & Associates?

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A. That's correct.
Q. Does Quick & Associates have any employees?
A. So, to clarify, Quick & Associates includes other unrelated businesses associated not with this, though, and there are employees of that -- those businesses.
Q. When you say "not with this," what do you mean by that?
A. Not associated with the consulting business.
Q. Okay. And what businesses are those?
A. Those would be businesses that my wife has related to equestrian matters.
Q. And those are housed under Quick & Associates --
A. That's right.
Q. -- as well?
A. They're sub -- they're sub -- they've got subnames, but that they're -- they're not -- they're separate.
Q. Would it be fair to refer to the consulting division of Quick & Associates or was there a better way to refer to that?
A. No, you can refer to Quick & Associates.

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Q. Okay. So, aside from the equestrian businesses that are within Quick & Associates, does Quick & Associates have any employees?
A. I'm the only person associated with Quick & Associates for the consulting aspect.
Q. Okay. So no employees other than potentially yourself?
A. That's correct.
Q. And are you -- you don't consider yourself an employee of Quick & Associates?
A. That's correct.
Q. Your primary focus within Quick & Associates has -- for the past few years, has been with 503(a) and 503(b) compounding pharmacies. Is that correct?
A. Among -- among other things.
Q. But you do state in your CV that the primary focus in the past several years have been with 503(a) and 503(b) compounding pharmacies. Correct?
A. That -- that's what it says, but there are a number of entities that I -- additional things that I do.
Q. Okay. So is it your testimony that that statement is not accurate?

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A. No, I'm not saying it's not accurate.
Q. Okay. So that has been your primary focus, but there are other activities that you engage in as well?
A. That's correct.
Q. On Page 3 of your CV, the second bullet point says: Engaged as independent expert witness on Q7A (API Quality).
What did that -- what did that matter involve?
A. That's the matter we discussed earlier.
Q. Which one? We discussed a few.
A. This was with the firm in California who was a contract manufacturer of monoclonal antibodies and there was an issue with one of their customers and I was called upon to prevent -- present an expert testimony relative to Q7A at the time.
Q. And the next bullet point below that in your CV says: Engaged as expert witness on aseptic processing in a litigation case.
Which case was that?
A. That was a case we discussed that occurred in 2012.
Q. And if you could just refresh my memory, that case in 2012, was that the medical device case?

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Was that a different case?
A. The one in 2012 was the aseptic processing case between the two private equity firms.
Q. Okay. Is -- is that the matter in connection with which you visited Teva or is that unrelated?
A. It -- it's unrelated.
Q. Okay. And then two bullet points down, do you see where it says: Have been preapproved by the FDA and DOJ to assist a drug company in a consent decree?
A. I do.
Q. What does that refer to?
A. That refers to a company in St. Louis that had been notified that the Department of Justice wanted to enter into a consent decree with the company.
Q. What do you mean when you say that you were "preapproved by the FDA and DOJ"?
A. So they had to provide to DOJ and FDA an individual who would be their consultant in regard to this matter, which they did.
Q. So they were free to choose?
A. I'm sorry?

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Q. They were free to chose whomever they wished as a consultant?
A. That's correct.
Q. And they simply needed to inform FDA and DOJ who that was going to be?
A. That's correct.
Q. And the second bullet point from the bottom still on Page 3 of your CV, mentions: Continued to work with former boss (past Baxter chairman/CEO) and his private equity company focused on the FDA regulated industry.
Who are you referring to there?
A. Vernon Loucks. I would note that he's recently passed away.
Q. Sorry to hear that.
Okay. And prior to beginning your consulting practice through Quick & Associates, you were with Baxter for a number of years. Correct?
A. That's correct.
Q. From 1966 through 2003?
A. That's correct.
Q. Other than your consulting work, is your time at Baxter your only employment within the pharmaceutical and medical device industry?
A. That's correct.

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Q. You've never worked for the FDA. Correct?
A. No, I have not.
Q. Looking at your list of papers, publications, presentations, and patents on Page 5, starting on Page 5 of your CV, Pages 5 and 6. The most recent one is November/December 2015. Is that correct?
A. That's correct.
Q. And there hasn't been anything more recent than that that isn't reflected here?
A. That's correct.
Q. Okay. The items here are a mix of publications and oral presentations. Is that correct?
A. That's correct.
Q. Did any of these relate to valsartan or valsartan-containing drugs?
A. No, they did not.
Q. Did any of these relate to nitrosamines?
A. No, they did not.
Q. Do you have any formal education in the regulatory or quality systems fields?
A. Formal education, no.
Q. Do any of your papers, publications, or

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presentations relate to testing for impurities?
A. No.
Q. Do you currently hold any professional licenses?
A. No.
Q. And I know you testified earlier you've never been employed by FDA. Have you ever done any consulting for FDA?
A. No.
Q. You're not a toxicologist. Correct?
A. No, I'm not.
Q. You're not an epidemiologist?
A. No, I'm not.
Q. You're not a cancer biologist?
A. No, I'm not.
Q. You're not a statistician?
A. No.
Q. You're not an analytical chemist?
A. I have a chemistry degree by education.
Q. Okay. Do you consider yourself an analytical chemist?
A. No.
Q. Do you consider yourself an expert in pharmacovigilance?
A. No.

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Q. Are you a medical doctor?
A. No.
Q. Will you be offering any opinions in this litigation about how nitrosamines are absorbed in the human body?
A. No, I am not.
Q. Will you be offering any opinions in this litigation about how nitrosamines are metabolized by the human body?
A. No, I will not.
Q. Will you be offering any opinions in this litigation as to whether or not valsartan is an effective drug in the treatment of hypertension?
A. No, I will not.
Q. Would it be fair to say that your opinions in this litigation are limited to your analysis of CGMP protocols?
MR. DAVIS: I'm going to object to the extent that that misrepresents his report.
You can answer to the question.
A. CGMP protocols, no. The answer is no.
Q. Okay. How would you describe the scope of your opinions in this litigation?
A. My opinions relate to the compliance aspects of the various companies related to CGMP as

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it pertains to the whole class action.
Q. Anything else?
A. It's -- it was the GMP aspects.
Q. And you won't be offering any causation opinions in this litigation. Correct?
MR. DAVIS: I'm going to object to the question.
You can answer.
A. Would you like to explain that?
Q. Sure.
You're not going to be offering any opinions in this litigation on whether defendants' products caused or contributed to any of plaintiffs' alleged injuries. Correct?
A. No, I'm not.
Q. Would it be fair to say that FDA plays an active role in regulation of pharmaceuticals and manufacture of pharmaceuticals?
A. Plays a role? Yes, that would be fair.
Q. And the FDA has a spectrum of available enforcement options. Correct?
A. Correct.
Q. That includes ordering a recall?
A. So, typically, FDA would not order a recall.

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Q. Does that --
A. They could do that.
Q. So they do have the power to do that?
A. They --
Q. Sorry. I just want to make sure that it's audible on the record. They do have the power to do that?
A. They do have the power. Well, maybe I should elaborate here, because that's not really the case.
If the FDA believes a recall should happen, they will say -- they will tell the firm that they recommend that the firm recall a product, and then the firm will voluntarily recall a product, usually.
Q. Does the FDA have the option of obtaining an injunction?
A. Going through the Department of Justice, yes.
Q. And does the FDA have the ability to stop a manufacturer from distributing a product?
A. If they go through the Department of Justice, they would have that authority.
Q. Does FDA have the power to seize product?
A. They do. It's not -- I'm not certain

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whether they have to go through the Department of Justice to seize the product or not, but they would typically do that, I believe. They do seize product.
Q. And does the FDA have the power to pursue criminal prosecution?
A. In conjunction with the Department of Justice, yes.
Q. Now, in your report, you discuss various FDA guidelines. Correct?
A. Guidances.
Q. Okay. Only guidances, no guidelines?
MR. DAVIS: I'll object to the question as vague.
A. So I'm not sure what I reference to what are guidelines. It's typically guidances.
Q. Okay. And is it your understanding that the terms "guidance" and "guideline" are distinct in discussing FDA -- in the FDA context?
A. Well, typically, it's guidances. I'm not -- if -- we'd have to -- we'd have to talk about what you mean, "guidelines."
Q. Are you familiar with FDA ever having issued something that is a guideline, rather than a guidance?

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A. Maybe. I don't recall.
Q. 21 CFR 210 and 21 CFR 211 set forth the CGMP for pharmaceutical products. Correct?
A. That's correct.
Q. And several of your opinions in this case refer to 21 CFR 210 and 211. Correct?
A. Correct.
Q. Is it fair to say that how a particular company achieves the controls described in 21 CFR 210 and 211 is up to the company to decide. Correct?
MR. DAVIS: Object to form.
A. As long as they're compliant.
Q. 21 CFR 210 and 21 CFR 211 don't set forth specific instructions on how to achieve the controls that are described therein. Right?
MR. DAVIS: Object to form.
A. The FDA -- FDA does describe those in the guidances that they have in terms of how you meet the requirements of 21 CFR 210 and 211.
Q. So focusing solely on 21 CFR 210 and 21 CFR 211, those do not set forth specific instructions on how to achieve the controls that are described therein. Right?
A. As you stated it, you're correct.

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MR. DAVIS: I'm going to object to that.
THE WITNESS: I'm sorry.
MR. DAVIS: Give me a few moments to object.
Q. Now, you mentioned a moment ago that FDA describes in guidances how you meet the requirements of 21 CFR 210 and 211. Is that correct?
A. That's correct.
Q. And what guidances are you referring to?
A. FDA has thousands of guidances, so I -- it's not just one guidance, there is -- there are many guidances.
Q. Are there any that you can think of, as you sit here today, that provide specific instructions on how to achieve the controls in 21 CFR 210?
A. There is gui- -- FDA has guidances on almost every aspect of 210 and 211, so...
Q. Okay. But as you sit here today, can you think of a guidance that set forths -- that sets forth specific instructions on how to achieve the controls that are described in 21 CFR 210?
MR. DAVIS: Object to form.
You can answer.

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A. So 210 and 211 cover a wide variety, a wide range of aspects, okay, and so for almost all of those, there would be a guidance.
Q. Okay. As you sit here today, can you --
A. Sure.
Q. -- identify one?
A. Sure.
FDA has a guidance on process validation.
Q. Okay. And what is that guidance?
MR. DAVIS: Are you asking for the cite or?
MS. ISIDRO: Yes.
A. So what do you mean, "what is that guidance," what --
Q. Is there a formal title or a citation for that guidance?
A. I don't -- it's -- process validation is the guidance.
Q. Okay. And does that guidance provide specific instructions on how to achieve the controls that are described with respect to process validation in 21 CFR 210 and 211?
MR. DAVIS: I'm going to -- same objection, and vague as to your use of the term "specific instructions."

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But you can answer.
A. It provides the guidance on how to conduct proper process validations for drug companies.
Q. Okay. So let me ask you this: Would a drug company be able to take the FDA guidance on process validation and implement it without having any manufacturer-specific processes or details included or added?
MR. DAVIS: Object to form.
A. So what a company should do would be they would develop standard operating procedures on how to meet the requirements and the guidances.
Q. And those standing -- standard operating procedures are a necessary part of the process for compliance with 21 CFR 210 and 211. Correct?
A. Correct.
Q. And those SOPs -- is it okay if we refer to standard operating procedures as SOPs?
A. Sure.
Q. Okay. Those SOPs would be drafted by each individual manufacturer. Correct?
A. Correct.
Q. They're not something that is issued in a standard format by FDA, ready to implement?

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A. That's correct.
Q. Okay. Your report discusses Form 483s. Correct?
A. That's correct.
Q. FDA can sometimes inspect a manufacturer's facility. Right?
A. That's correct.
Q. And that's commonly referred to as an FDA site inspection?
A. Yes.
Q. And upon conclusion of a site inspection by FDA, the FDA investigator may issue a Form FDA 483, based on what was observed during the inspection. Correct?
A. That's correct.
Q. Would you agree that Form 483s are relatively common in the industry?
MR. DAVIS: Object to form.
A. Well, the term -- what do you mean, "relatively common"? Many companies do not get a Form 483 after an inspection.
Q. During your time at Baxter, did they ever receive a Form 483?
A. Yes.
Q. And an FDA Form 483 is a list of

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observations made by the FDA inspector during the inspection and presented to the most responsible person of the inspected facility at the close of the inspection. Correct?
A. Correct.
Q. FDA 483 inspectional observations are considered to be the opinion of the FDA investigator. Correct?
MR. DAVIS: Object to form.
A. Typically, before a FDA 483 is issued, the investigator will confer with the center or his office before issuing that. So it would be probably the opinion of the investigator, but also conferring with the office.
Q. FDA Form 483s do not represent a final agency determination regarding compliance. Correct?
A. That's correct.
Q. Your report also discusses warning letters. Is that right?
A. That's correct.
Q. A warning letter is sometimes issued by the FDA as a result of an inspection and issuance of a Form 483?
A. That's correct.
Q. But a warning letter does not always

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follow a Form 483. Correct?
A. That is correct.
Q. Are Form 483s and warning letters issued by the same division within FDA?
A. I'm not sure I know what you mean by "division."
Typically the drug group would handle the drug aspects. You wouldn't get a warning letter on a drug product from the medical device group, for example.
Q. Okay. Are you familiar with the Office of Regulatory Affairs within FDA?
A. Yes.
Q. Does the Office of Regulatory Affairs issue Form 483s?
A. They can.
Q. Does the Office of Regulatory Affairs issue warning letters?
A. They can. Typically it would come from the local office -- or the district office or regional office.
Q. Are you familiar with the FDA's regulatory procedures manual?
A. I've seen it, yes. I've looked at it, I've reviewed it. It's extensive.

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Q. And are you aware that the FDA's regulatory procedure manual states that a warning letter is informal and advisory?
A. I think it says more than that, but we'd have to go back and look at exactly what it says.
Q. Would it be fair to say that a warning letter communicates the agency's position on a matter, but it does not commit the FDA to taking enforcement action?
MR. DAVIS: Object to form.
A. It does not commit the FDA to take an enforcement action beyond that.
Q. And the FDA itself does not consider warning letters to be final agency action on which it can be sued. Is that correct?
MR. DAVIS: Object to form.
A. There are additional actions beyond the warning letter.
Q. After a warning letter is issued, the FDA reviews a manufacturer's response to the warning letter. Correct?
A. Usually.
Q. And what do you mean by "usually"?
A. I mean, they can take action without reviewing that.

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Q. What sorts of actions could they take without reviewing that?
A. Well, they could go directly to some sort of a consent decree or seizures or some other action, depending on what it is. But they would usually review the warning letter response.
I will note, though, in many warning letters they will put the fact that they're going to initiate an import detention for those firms that reside outside the United States in the warning letter.
Q. What does that entail?
A. That means that those products from that company cannot be imported to the United States.
Q. So when the FDA reviews a company's response to a warning letter, if the FDA is satisfied with the company's response, does it close out the warning letter?
MR. DAVIS: Object to form.
A. No, not usually.
Q. So what happens once the FDA has reviewed a company's response to a warning letter and the FDA is satisfied with the response?
A. They won't be satisfied until they come back for an additional inspection, usually.

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Q. And what is that based on, your statement that they won't be satisfied usually until they come back for an inspection?
(Simultaneous speaking.)
A. The typical action by the FDA, in order to close out a warning letter, is that they will come back and do an inspection. That's the typical response from the FDA.
Q. And when you say "that's the typical response from the FDA," is that based on your experience?
A. Yes.
Q. Based on anything else?
A. Well, it's based on what they do. It's just history.
Q. So just what you've observed over the years in this industry?
A. Yes.
Q. In your report in this litigation you refer to nitrosamines. Correct?
A. I do.
Q. And are the nitrosamines you're referring to NDMA and NDEA?
A. Yes.
Q. What sources did you learn to -- what

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sources did you use to learn about nitrosamines in connection with this litigation?
A. I reviewed the documents that were provided by the company in response to my request.
Q. And when you say "the documents that were provided by the company," what company are you referring to?
A. The defendants.
Q. So you reviewed documents produced by the defendants in this litigation?
A. I did.
Q. Did the documents that you reviewed include information about levels of impurities found in each manufacturer's product?
A. Well, we're talking a number of defendants. Some did, yes.
Q. Did you review nitrosamine levels for each defendant's products?
A. No. What I was tasked to do was to determine the CGMP compliance of the various companies.
Q. And does that mean that you do -- you would not view the levels of nitrosamines in the product as relevant to that inquiry?
MR. DAVIS: Object to form;

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mischaracterizes his testimony.
A. Well, they're probably relevant because that's the basis for many of the issues that the FDA had with the companies.
Q. So you did not review nitrosamine levels for each defendant's products, but you do view that information as relevant to your opinions?
MR. DAVIS: Object to form;
mischaracterizes his testimony.
A. No, I don't consider it to be relevant. What I consider to be relevant are the CGMP aspects of the various companies. That was one component of it, but it wasn't the determining factor for CGMP.
MS. ISIDRO: Let's go ahead and take a short break, five minutes.
MR. DAVIS: Sure.
THE VIDEOGRAPHER: Off the record. The time is 11:33 a m.
(Break.)
THE VIDEOGRAPHER: We're back on the record at 11:46 a.m.
Q. Mr. Quick, one of the documents that you relied on in your report was the FDA's guidance to manufacturers of human drugs on controlled nitrosamine impurities. Correct?

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A. If I reference -- I have to go back and look. If I reference it there, yes. I don't recall that, but, yes.
Q. Well, let's take a look at your reliance list in your report.
A. Yes, I do see it.
Q. Okay. It's on Page 3, right, the second item from the top?
A. Right.
Q. Yeah. Okay. Now, that guidance was not released until 2021. Correct?
A. Yes. That's the date that's stated here. I don't know whether there is an earlier version of it or not, but...
Q. Okay. So as you sit here right now, you don't know one way or the other whether there was an earlier version of the FDA's guidance on control of nitrosamine impurities in human drugs?
MR. DAVIS: I'm going to object to form and vague and ambiguous for draft or final.
A. I'm not certain.
Q. Are you aware of whether the FDA had set any interim limits on nitrosamines?
A. I didn't -- I didn't review the limits that the FDA has set. What I was reviewing were the

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CGMP aspects as it applied to all of the class group. That's what I was reviewing. And the particular limits of the nitrosamine was not relevant to the CGMP aspect.
Q. So as you sit here today you don't know one way or the other whether there was an FDA standard requiring testing for nitrosamines in the 2012 to 2018 period?
A. There was a requirement for the manufacturers to know their impurities and to characterize the impurities that they would find in the product.
Q. But as you sit here today, you don't know one way or the other whether the FDA had a standard requiring testing for nitrosamine specifically in 2012 to 2018?
MR. DAVIS: I'm going to object to the form.
A. Again, as I stated, the FDA's expectation was that the manufacturers would characterize the impurities and define the impurities. That was the expectation.
Q. Would that be part of the compendial standards for a product?
MR. DAVIS: Object to form.

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A. Well, it's a requirement for under Q7A that you would know your impurity profiles.
Q. And where would impurity profiles for a particular product be set forth?
A. I didn't catch the last part of that.
MS. ISIDRO: Can you read it back, please?
(The requested material was read.)
A. Well, the manufacturer is supposed to set forth their own impurity profiles.
Q. And where would the manufacturer do that? Is that part of a submission to the FDA?
A. It could be, but they're supposed to know their own impurity profiles. I mean -- so the FDA would not know what those are. The manufacturers would know or should know.
Q. Okay. And are there specific standards that are set forth for the composition of a particular drug product?
MR. DAVIS: Object to form.
You can answer.
A. Well, there are USP monographs. And the FDA -- the firms would put into their files what they're going to do and the FDA would determine whether those are acceptable for that or not.

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But I don't know. There's -- I'm not sure I understand exactly your use of the word "standards."
Q. Sure. Does USP set forth testing requirements for impurities in a particular drug product?
MR. DAVIS: Object to form; Incomplete question.
A. They may. I'm not certain. But Q7 does. That was the real point.
Q. What determines the particular impurities that a manufacturer has to test for with respect to a specific drug product?
MR. DAVIS: Objection; vague. Are you referring to impurities or genotoxic impurities?
Q. You can answer the question.
A. Sorry. Would you repeat the question?
MS. ISIDRO: Can you read it back, please?
(The requested material was read.)
Q. That's --
MR. DAVIS: Same objection; vague.
A. Manufacturer is supposed to characterize their impurities and know what they are.
Q. How does that get implemented into the

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manufacturing process?
MR. DAVIS: Object to form. That -- vague.
A. I'm not sure I understand what you're trying to go with, with that.
Q. So it's your testimony that a -- it's our testimony that a manufacturer is supposed to characterize the impurities associated with a particular drug product to know what they are. Correct?
A. That's correct.
Q. What happens once a manufacturer identifies impurities during that process?
A. Well, it depends what the impurities are and determines what actions they should take. They need to know what they are in the first place.
Q. Okay. Are you familiar with the concept of compendial standards for a pharmaceutical product?
A. Compendial products? Are we talking about USP? Is that what we're talking about?
Q. Just -- is -- is that what it means to you?
MR. DAVIS: If he --
A. I don't use that term.

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MR. DAVIS: He's asking for a clarification.
Q. What term do you use?
A. USP monographs.
Q. USP monographs.
Are impurities addressed within USP monographs for a direct product?
MR. DAVIS: Objection to form and vague as to the use of the word "impurities."
A. I'd have to go back and review that. The key point is they're addressed in Q7 as to -- as to what a manufacturer should do.
Q. As you sit here today, do you know whether any -- do you know whether USP monographs for any valsartan-containing product set forth any standard for testing for nitrosamines in the 2012 to 2018 time period?
MR. DAVIS: Object to form.
You can answer.
A. I didn't review that and it wasn't necessary to review that based on the fact that I was looking at the CGMP aspects as it pertained to the class group.
Q. Okay. So you did not view USP monographs as relevant to the scope of your opinions?

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A. No, I -- I didn't say that. I'm saying I just didn't review that.
Q. Okay.
A. The -- the other thing I would add is what I have in the report are examples. It's not an exhaustive list.
Q. We're going to get to the examples in your report in -- in due course.
Are you aware that in 2018 FDA stated that: The presence of NDMA was unexpected and was thought to be related to changes in the way active substance was manufactured?
MR. DAVIS: Object to form.
A. I don't recall that exact term.
Q. Did you review the July 2018 statements that FDA issued regarding nitrosamines?
A. I may have. I don't recall those.
MR. DAVIS: And I'll object to that as vague. There were plenty of statements from the FDA in 2018.
MS. ISIDRO: I'm going to mark as Exhibit 8 an August 30, 2018, statement from FDA on FDA's ongoing investigation into valsartan impurities and recalls and an update on FDA's current findings.

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(Exhibit 8 was marked.)
Q. Have you seen this document before, Mr. Quick?
A. I may have, I'm not certain.
Q. As you sit here today, you can't recall one way or the other?
A. Well, there are a lot of documents on this subject so I may have seen this.
Q. But you don't recall specifically as you sit here today?
A. I don't recall specifically this document.
Q. I'm going to turn your attention to the third page of this press -- of this statement, excuse me. And I'm going to draw your attention to the second paragraph from -- excuse me.
I'm actually going to draw your attention to the last paragraph at the bottom of that page. About halfway through that do you see where it says: Before we undertook this analysis, neither regulators in our industry fully understood how NDMA could form during this process?
A. I see that.
Q. So this was not something that FDA understood --

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MR. DAVIS: Object to form.
Q. -- previously?
MR. DAVIS: And calls for speculation as well.
A. Well, I'm not going to speak for FDA. I can read this -- what it said. What it stated here.
Q. Is it your understanding that FDA is saying that is -- it is acknowledging that it did not understand it previously?
MR. DAVIS: Object to form, and calls for speculation.
A. That -- that -- I'll read you what it saws here: Before we undertook this analysis, neither regulators in our industry understood how NDMA could form during this process.
That's what it says.
Q. And, in fact, FDA did not initially have the analytical capability to measure nitrosamine impurities. Isn't that right?
MR. DAVIS: Object to form.
A. I don't know.
Q. Well, let's take a look at the second full paragraph on the third page of this statement. That references F -- the fact that: In St. Louis the FDA maintains the most advanced pharmaceutical

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laboratory of any regulatory agency in the world.
Correct?
A. That's what it says.
Q. And further down in the paragraph it states that: To determine if valsartan products do contain the NDMA impurity, CDER scientists have now developed the gas chromatography mass spectrometry head space testing method.
Correct?
MR. DAVIS: Are you asking if he sees that?
A. I see that, yes, if that's what you're asking.
Q. So, in fact, FDA scientists had to develop a new method in order to determine whether valsartan products contained NDMA?
MR. DAVIS: Object to form, and mischaracterizes the statement.
A. I'm not -- I'm not going to say I --
MR. DAVIS: Let me finish my objection first. Yeah. Object to form, and mischaracterizes the statement in the document.
You -- you can answer. It's okay.
A. So I see what it says here, but I'm not going to speak for the FDA.

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Q. Are current industry standards relevant to current good manufacturing processes?
MR. DAVIS: Object to form.
You can answer if you understand it.
A. If you want to talk about industry, what industry standards you're referring to?
Q. Are pharmaceutical industry standards relevant to current good manufacturing practices in the pharmaceutical industry?
A. So you need to describe what you mean by pharmaceutical standards, industry standards. That's not -- that's not a typical term that would be used.
Q. Okay. Are current testing capabilities relevant to the question of current good manufacturing practices in the pharmaceutical industry?
A. Probably not.
Q. Why not?
A. Because we're talking about current good manufacturing practices, we're not talking about testing methods.
Q. Testing methods are completely irrelevant to good manufacturing practices?
A. I did not say that.

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Q. Okay. Then help me understand why, because we're talking about current good manufacturing practices and not testing methods, testing capabilities are not relevant to current good manufacturing practices?
MR. DAVIS: Object to the form, and mischaracterizes his testimony.
A. Testing capabilities and good manufacturing practices are two different things.
Q. Okay. Is -- they are two different things. Are they relevant to each other?
MR. DAVIS: Objection; vague.
You can answer.
A. I'm not going to say there's no relevance, but I'm just saying they're two different things.
Q. If a test doesn't exist, can it form part of current good manufacturing practices?
A. Well, if a -- what you said makes no sense.
MR. DAVIS: Object to the hypothetical, is contrary to --
A. What you just stated really makes no sense.
Q. Why doesn't it make sense?

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A. If something doesn't exist -- you want to elaborate more what you're trying to say?
Q. Well, if something doesn't exist, it can't form part of good -- current good manufacturing practices. Right?
MR. DAVIS: Object to form, and presenting an improper hypothetical.
A. I'm not sure where -- where you're going with this, but they're not relevant to each other based on what you're saying.
Q. So you won't agree with me that if something doesn't exist, it cannot form part of current good manufacturing practices?
MR. DAVIS: Object to form, that mischaracterizations his testimony.
You can answer.
A. If some -- if something doesn't exist, then it obviously wouldn't be part of anything.
Q. What is your understanding of adulterated products in the context of pharmaceutical regulatory compliance?
A. If a firm fails to meet CGMPs -- there are several aspects. If a firm fails to meet CGMPs, the product -- the products that they make in that facility would be considered -- would be considered

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to be adulterated.
Q. That is your complete understanding of the term "adulterated products" in the pharmaceutical context?
A. No --
MR. DAVIS: Object to form, if you want him to look at his report, he's willing to look at his report.
A. Yeah. I -- I -- I go into that in the report. There are other aspects of adulteration.
Q. My question to you what is -- was, what is your understanding of the term "adulterated products" in the pharmaceutical context?
MR. DAVIS: Object to form.
You can answer.
A. So a product could be contaminated, that would be adulteration. Or the product could be fine but if the firm failed to adhere to current good manufacturing practices, the products that they are making, by definition are adulterated.
Q. Does FDA define adulterated products?
A. I just defined it.
Q. My question was, does FDA define it?
A. They do. The FDA states if the firm is not manufacturing products in accordance with the

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current good manufacturing practices, the products are adulterated.
Q. Is there a particular regulation or other place where FDA defines adulterated product?
A. It states it many places. And I think I reference those in the report.
Q. Okay. Can -- do you still have your report --
A. Yes.
Q. -- in front of you?
Can you show me where you reference that?
A. Okay. We'll have to go through here and find it.
(Pause.)
Well, Section -- my Section 24 refers to that.
MR. DAVIS: For the record, are you on Page 6, Mr, Quick?
THE WITNESS: Yes, on Page 6.
MR. DAVIS: Okay.
Q. Does FDA also define the term "misbranded"?
MR. DAVIS: Object --
A. That's separate.
MR. DAVIS: Hang on, Mr. Quick. Let

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me place an objection on the record.
So I'm going to object to form, and vague as to your term -- use of the term "FDA defining" something.
You can answer, Mr. Quick.
THE WITNESS: So what was --
MS. ISIDRO: If you could read back the question and the answer that Mr. Quick started to give before the objection.
(The requested material was read.)
A. So I'm not sure I understand the question.
Q. Well, you said "That's separate." What do you mean?
A. Yeah, I -- that was, like, five minutes ago. So, I mean, you may want to rephrase your question.
Q. Does FDA define the term "misbranded" in the pharmaceutical context?
MR. DAVIS: Object to form, and same objection as to the use of the word "FDA defining" something.
A. Well, I've discussed misbranding in the report here, and we can probably pull that up.
(Pause.)

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So relative to misbranding, on 27: A drug product may be declared misbranded if the label is false or misleading in any -- in a way which fails to reveal facts material with respect to consequences which may result from use of the article.

There may be another place, too.

(Pause.)

Q. You said there may be another place, too. Did you find another place?

A. There may be, but I think that covers it.

Q. Okay. What do you understand to be the difference between the terms "adulterated" and "misbranded" in the pharmaceutical context?

A. Well, if a product is misbranded, it's considered to be adulterated. Adulterated product doesn't necessarily have to be misbranded.

Q. Can you explain that further?

A. What would you like me to explain?

Q. Well, is that the only difference between the terms?

A. Well, as I said a few minutes ago, is I explained to you how a product can be considered to be adulterated.

Q. Okay.

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MR. DAVIS: And please let me get some objections on the record.

And I'm going to object to form on that.

You can answer.

THE WITNESS: Okay.

A. As I previously stated, a product can be considered to be adulterated if the CGMPs were not followed in the manufacturing of the product, even if there is nothing wrong with the product.

Q. What is your basis for that statement?

A. FDA states that in numerous places.

Q. Okay. Can you identify one place where FDA states that?

A. Okay. Well, one good example is virtually every single warning letter states in the warning letter, because CGMPs were not met, the product is considered to be adulterated.

Any warning letter -- all the warning -- we can pull up any of the warning letters we're talking about, and we would see that.

Q. Any other basis for your statement with respect to CGMPs and adulteration?

MR. DAVIS: Just for clarification for my purposes. I might be lost here. What's the statement exactly?

(Discussion off the written record.)

(The requested material was read.)

MR. DAVIS: Thank you.

So what's -- is there a question pending right now?

MS. ISIDRO: Can you read back the last question, please?

(The requested material was read.)

A. So as I've indicated, the FDA states that. They also -- in almost virtually every warning letter that's issued to a firm, they will say in the warning letter that the product is considered to be adulterated because CMG -- CM -- they were in violation of CGMPs.

Q. Can you point to any warning letters where FDA says that one product is adulterated because of CGMP violations in connection with a different product?

A. So -- okay.

(Pause.)

Well, the examples in the warning letters refer to the facility. They don't refer to specific products.

So, I mean, we could pull up any warning letter, and it would say that.

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The other point I would pull up here, which I state in my report relative to FDA's statement. This has to do with -- they say if -- this is No. 34: FDA has formalized this in the active pharmaceutical ingredient (API) process inspection manual to further state "A firm is not in a sufficient state of control if any one system as defined in this program is found to be significantly noncompliant of CGMPs such that the quality, identity, and purity of the API resulting from that system cannot be adequately assured."

Q. What paragraph in your report are you reading, sir?

A. 34.

(Reporter admonishment.)

Q. You cite to some sources in that Paragraph 34 that you were reading from. Correct?

MR. DAVIS: Excuse me, Counsel. Somebody was shuffling paper when you asked the question. It was inaudible on our end.

MS. ISIDRO: That was the witness.

Can we have that question read back, please?

(The requested material was read.)

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A. Correct.
Q. Are those the sources from which you obtained the quotes that you have in Paragraph 34?
A. The quote -- I'm not sure which one of those footnotes references where the quote came from. I'd have to go back and look at these specific ones, but it came from an FDA source.
Q. One of the sources that you cite there is a 2005 PowerPoint presentation. Is that correct?
A. That's correct. But the other one is the compliance program manual. That's the API Compliance Program Manual.
Q. And the statement that you're -- which of the quotes are attributable to the program manual in Paragraph 34?
MR. DAVIS: Do you want him to look at the program manual?
MS. ISIDRO: Well, he's saying that that's where they came from, so I'm asking him to identify which ones came from that source.
MR. DAVIS: Well, I think he said that some of them came from that source.
A. If we could pull up the document, we could look at it, and I could show you.
(Exhibit 9 was marked.)

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MS. ISIDRO: And we are marking as Exhibit 9 FDA Compliance Program Guidance Manual 7356.002F.
MR. DAVIS: Do you want to take a few minutes to review the document?
THE WITNESS: Yes.
A. (Pause.)
So if we look at Page 8 and 9 in this document, it refers to the various systems on Page 8 and 9.
Q. Uh-huh.
A. And if we go back to Page 7 --
Q. Let me make sure I'm following you. So Page 8 and 9?
A. Describes the systems.
MR. DAVIS: Is there a question pending? You're not being asked to just describe the document. You're supposed to respond to questions.
Q. You may continue.
MR. DAVIS: Well, no, no. He has to -- he's only here to respond to your questions.
Q. You started to say, "So if we look at Pages 8 and 9 in this document, it refers to the various systems."

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Are you referring to the enumerated list on the bottom of Page 8 and the top of Page 9?
A. I am. And if we go back -- if we go back to Page 7, and if we look at the second paragraph: A firm is not in a sufficient state of control if any one system as defined in this program is found to be significantly noncompliant with CGMPs, such that the quality, identity, and purity of the API resulting from the system cannot be adequately assured.
Q. Now, that quote that you just read, that refers to significantly noncompliant with CGMPs. Correct?
A. It says -- that's what it says.
Q. It's not simply any noncompliance with CGMPs. Correct?
A. It says -- it does say "significantly noncompliant."
Q. So how does that statement provide a basis for your conclusion that any CGMP noncompliance causes all products from a particular facility to be considered adulterated?
MR. DAVIS: Object to form, mischaracterizes his testimony.
You can answer.

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Q. And if I'm mischaracterizing your opinion, please feel free to correct me.
A. So I'm reading here what this guidance document says. What I'm referring to in my report, relative to the class group that we're talking about, has to do with CGMPs.
I'm just making the point here as to what FDA says about any one of the systems.
Q. Okay.
A. That was the -- put in the context of good manufacturing practices.
Q. But you say in Paragraph 32 of your report that: FDA's official position regarding CGMPs is that if a company is not complying with CGMP regulations, any drug it makes is considered adulterated under the law.
A. Right.
Q. So where is your basis for that statement?
A. So I go back to -- we can pull up -- there is other guidance documents. I just probably didn't reference it here. You pull up any warning letter, we're talking about right in the body, the first body -- the first part of the warning letter, it will talk about the products that are considered

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to be adulterated.
MR. DAVIS: And, again, object to the form.
Q. Do you have any support for that statement in Paragraph 32, other than the body of warning letters?
MR. DAVIS: The footnote.
MS. ISIDRO: I'm sorry. Are you testifying?
MR. DAVIS: I mean, it's just obvious. He's cited it in his report.
MS. ISIDRO: Are you testifying?
MR. DAVIS: Okay. You can answer the question.
A. I think it's -- I think it's actually -- let's see here. Yes, it's Footnote 8. So if we can pull up Footnote 8 --
Q. Okay.
A. -- that document.
UNIDENTIFIED SPEAKER: Which document are you referring to?
MR. DAVIS: It's not been marked as an exhibit yet.
Q. Let's mark this as Exhibit 10.
MR. DAVIS: 10.

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(Exhibit 10 was marked.)
Q. Okay. I am handing you what's been marked as Exhibit 10. Is this the document that's cited in Footnote 8?
A. It is.
Q. Okay. Now, can you show me --
A. Sure. Go to Page 2.
Q. Okay.
A. The last section in that page, the second paragraph from the bottom.
It says: If a company is not complying with CGMP regulations, any drug it makes is considered adulterated under the law. This kind of adulteration means that the drug was not manufactured under conditions that comply with CGMP. It does not mean that there is necessarily anything wrong with the drug.
Q. And that applies with respect to any drug for which the CGMP regulations were not followed.
Correct?
A. No, that's not correct. That's not what I said. That's not what this says. You said something different.
Q. So any CGMP observation with respect to any system does not automatically render a product

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adulterated. Correct?
A. No --
MR. DAVIS: Object to form.
A. -- that's not correct.
THE WITNESS: I'm sorry.
MR. DAVIS: Sorry.
A. That's not correct.
Q. Is it your opinion that a single minor observation about a single product line in a 483 represents the FDA's determination that all products manufactured at that facility are adulterated?
MR. DAVIS: Objection; improper hypothetical.
You can answer.
A. That's not what I've stated. What I'm stating is what FDA has stated. Okay? And I'll say it again.
If a company is not complying with CGMP regulations, any drug it makes is considered adulterated under the law. That's what the FDA states. That's not what John Quick states. That's what the FDA states.
Q. And, again, those would have to be significant CGMP violations, significant enough to rise to that level. Correct?

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A. It doesn't say that. It doesn't say that here.
Q. Okay.
A. Okay.
Q. But the other document we looked at does. Correct?
A. That was the document for Q7. They're different documents.
Q. Right. But the other document did say that. Correct?
MR. DAVIS: For the record, are you referring to Exhibit 9?
Q. The FDA compliance program manual?
A. Right.
Q. Exhibit 9. Correct?
A. No, Exhibit 11. I think it's Exhibit -- no. Yeah, it is. It's Exhibit 9 and 11.
MR. DAVIS: You're referring -- just for clarification, I believe the witness is referring to Footnote 11, which is marked as Exhibit 9.
Q. The FDA compliance program manual, 7356.002F. Correct?
A. Right.
Q. To determine if a product is adulterated

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due to CGMP violations, you would need to look at the specific violations. Correct?
A. Well, again, I'll go back to what it says here. It doesn't say that, okay, in terms of that. So it doesn't say whether it's a minor thing or major. It doesn't say that here. Okay?
But -- and the situation we're talking about here, for the companies we're talking about -- and eventually we're probably going to get into that -- is that there were a number of situations, a number of examples I had here where there were CGMP violations.
And, again, those are the things that the FDA refers to as being adulterated. I was trying to put it into the context of what you asked relative to where the reference was with the FDA.
Q. So, again, I just want to make sure that I understand what your position is.
Is it your position that any individual CGMP violation renders each and every product that is manufactured at that facility where that CGMP violation occurred adulterated?
MR. DAVIS: Objection to form; mischaracterizes his testimony so far in his report.
A. That's not what my report --

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(Simultaneous speaking.)
MR. DAVIS: You can answer.
THE WITNESS: I'm sorry.
MR. DAVIS: Wait for me to finish my instruction.
Mischaracterizes his testimony and his report.
You can answer.
A. So that's not what my report says. My report basically says that I'm referring to the CG -- you're putting your hand up.
My report says that I'm referring to the CGMP violations of the company relative to the class group. That's what I'm referring to. I don't get into the fact that those are adulterated. I don't say that. I'm just talking about the violations as they apply to the class group. I'm just referring to what the FDA refers to -- as to these as, as being adulterated.
Q. So you're not rendering an opinion as to any -- as to whether any product was adulterated?
MR. DAVIS: Objection to form; mischaracterizes his testimony and his report.
A. So I'll say again what I just said, is I'm referring to the GMP violations of the various

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companies relative to the class group, okay, in regard to these various companies. And I'm pointing out the FDA's interpretation of that is you have the CGMP violations, the products are considered to be adulterated.
I didn't say that the FDA says that for CGMP -- CGMP violations. I'm not saying that these products are adulterated. I'm saying that they violated -- that they were not in compliance with CGMPs.
Q. So you're not saying that any valsartan-containing drug was adulterated?
A. No, I do not.
MR. DAVIS: Objection.
THE WITNESS: Sorry.
MR. DAVIS: And mischaracterizes his report.
A. I didn't say that.
(Discussion off the written record.)
(The requested material was read.)
Q. I just want to make sure -- withdrawn. So just to clarify, are you stating that it is the FDA's position that a single minor observation about a single product line in a 483 represents FDA's determination that all products

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manufactured at that facility are adulterated?
MR. DAVIS: Counsel, I'm going to go -- you're reading the exact same question you read two minutes ago. It's asked and answered.
You can answer it one more time, Mr. Quick.
A. Okay. So I'm not going to characterize the FDA's interpretation of anything. I'm just telling you what the FDA says about CGMP violations. You're imposing a specific situation, which is not what FDA -- that's not what the FDA says here. I'm just telling you what the FDA does say about CGMP violations relative to adulteration.
You're asking a question that's not posed there.
Q. Did you review specific CGMP violations here?
A. "Here" what?
Q. In connection with this litigation.
A. I'm sorry. In conjunction with what?
Q. In connection with this litigation.
A. Yes.
THE VIDEOGRAPHER: I need to start a new file. Can we take a break?
MS. ISIDRO: Yes, we can take a

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break.
THE VIDEOGRAPHER: Off the record, 12:38 p m.
(Break.)
THE VIDEOGRAPHER: We are back on the record at 1:27 p.m. This marks the beginning of Media Unit 2.
Q. All right. Mr. Quick, you still have Exhibit 6 in front of you, which is your report in this litigation. Correct?
A. Right.
Q. Is it fair to say that roughly the first half of your report, through Paragraph 100 on Page 20, is it fair to say that that portion of your report recounts your understanding of the FDA's regulatory policies and procedures?
MR. DAVIS: Object to form.
You can answer.
A. Yes, I believe that to be the case.
Q. Okay. And then the remainder of your report addresses specific issues with various defendants in the present litigation. Correct?
A. Yes.
Q. Okay. Now, we've talked about Exhibit A to your report.

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A. Which exhibit?
Q. Exhibit A to your report, the materials relied upon for your declaration.
Did you put this list together yourself?
A. Well, I -- I believe that this list represents the footnotes that I used -- referenced in the report. It's a summary of that. I didn't specifically put this compilation together. I think those -- that was a compilation of what was in the footnotes.
Q. So who created that compilation for you?
A. I think it would have been the law firm.
Q. And what about the report itself, did you draft the report itself?
A. Yes.
Q. On your own?
A. Yes. Let me, I'll clarify, there was some formatting things that -- and the group reviewed it, there was some formatting points that they made in the -- in the report.
Q. But as far as putting pen to paper or keys to keyboard --
A. It was my --
Q. -- that was you?
A. I did.

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Q. Okay. Now, on Exhibit A, the materials relied upon for your declaration, there are a number of documents that were produced by the defendants in this action. Correct?
A. That -- that is right. Yes.
Q. But these are not all of the documents that were produced by the defendants in this action. Correct?
A. That is right, yes.
Q. Okay. And how did you determine which documents would be listed on your reliance list and which ones would not?
MR. DAVIS: Object to form.
A. Well, there was no specific conscious determination as to which ones. I went through the various GMP issues and I used the documents to refer to those as part of the documents that I relied on.
And, again, the point -- like I said this morning, these are just examples.
Q. When you say "these are just examples," what are you --
A. The C --
Q. -- referring to?
A. The CGMP issues.
Q. And you're referring now to the

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discussion after Paragraph 100 of your report?
A. Yes.
Q. Paragraphs 101 through 191 of your report?
A. Yes.
Q. And you testified earlier that everything that you relied on is either in the Exhibit A to your report or in the footnotes to your report. Correct?
A. Yes.
(Discussion off the written record.)
Q. Before marketing a new drug, the manufacturer's sponsor has to submit a new drug application to the FDA. Correct?
A. Or an abbreviated new drug application.
Q. Okay. But this is for a new drug?
A. Oh, new drug, yes. New drug.
Q. So new drug, new drug application. Correct?
A. That is right.
Q. Okay. And the new drug application has to demonstrate that the medication meets statutory standards for safety and effectiveness. Correct?
A. Yes.
Q. And it also has to establish that it

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meets manufacturing and controls and labeling and so forth?
A. There are a number of things, among other things, yes.
Q. And the FDA has to grant its approval to that new drug application before the new drug product can be marketed. Right?
A. Yes. The FDA has to approve the application, yes.
Q. Okay. And a manufacturer of a generic drug must submit an abbreviated new drug application. Correct?
A. There -- there's some other possibilities, but typically it would be an abbreviated new drug application.
Q. Okay. And what are the other possibilities you're --
A. Well, I think that's a 5 --
Q. -- referring to?
A. I think it's 5 -- 503, 505(b)(3) or something like that. But typically, it'd be an ANDA.
Q. And the generic drug can only be marketed after the FDA approves that application. Correct?
A. That's right.

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Q. In order to obtain approval of an ANDA, an applicant has to include, among many other things, information to show that the drug is bioequivalence to the reference listed drug. Correct?
A. Well, they've got to show it's therapeutic equivalent and bioequivalence is part of that.
Q. So bioequivalence is one of the things --
A. Right.
Q. -- they have to show. Right?
A. Yes.
Q. Okay. And I'll just remind you, I know we just came back from the lunch break, but I'll just remind you to please wait until I finish my question before starting your answer just so that the court reporter can make sure that everything is recorded accurately on the record. Thank you.
And an ANDA applicant also has to include information showing that the active ingredients of the proposed generic drug are of the same pharmaceutical or therapeutic class as those in the RLD. Right?
A. Well, they have to show that they contain identical amounts to the identical active drug

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ingredient.
Q. Have you reviewed the ANDA for any valsartan-containing drug products?
A. I don't believe so.
Q. Have you reviewed any of the bioequivalence data associated with any of the ANDAs for valsartan or valsartan-containing products?
A. I don't believe so. That was -- that was not within the scope of what I was looking at.
Q. Okay. When a drug comes to market via the ANDA process, the ANDA applicant typically doesn't have to con -- to conduct or include additional preclinical or clinical safety and efficacy trials. Correct?
A. They could. I'm not -- I'm not opining on what -- what they may or may not have to do. FDA will ask questions when they're going through the review process and -- so I'm not going to say there would not be that possibility.
Q. But under the -- the ANDA process, generics are typically granted approval status based on the safety and efficacy data that was previously submitted by the drug innovator or the ANDA holder. Right?
A. That's my understanding, but that's not

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what I'm opining on, though.
Q. Okay. Are you aware of how FDA defines active ingredient?
A. Active ingredient is the ingredient that's intended to treat the patient as opposed to an inactive ingredient.
Q. Would any component that provides pharmacologic --
MS. ISIDRO: I'll withdraw that question. Let's pause for a moment. Just go off the record for a moment.
THE VIDEOGRAPHER: Off the record, 1:37 p m.
(Break.)
THE VIDEOGRAPHER: Back on the record, 1:39 p.m.
Q. Would you agree that any component that provides pharmacologic activity or other direct effects in the diagnosis, cure or mitigation, treatment or prevention of disease or to affect the structure or any function of the body, would qualify as an active ingredient?
MR. DAVIS: Objection.
You can answer.
A. That sounds reasonable, but that's not

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what I'm opining on.
Q. Okay. And while an ANDA approved drug will have the same active ingredient as the reference listed drug, it may contain different inactive ingredients as long as they don't interfere with achieving bioequivalence of the active ingredient --
MR. DAVIS: Objection.
Q. -- right?
MR. DAVIS: Object to form, and misrepresents the -- the law.
You can answer.
A. So it -- it probably depends upon what it is in terms of the application process. The FDA may object to something. I don't know. It -- we're trying to generalize something that might be specific to a very individual drug.
Q. Would you agree that FDA does not require the inactive ingredients of an ANDA approved drug to be identical to the inactive ingredients of an NDA approved drug?
A. I believe that to be correct but, again, that's not what I'm opining on.
Q. Would you agree that each manufacturer of valsartan in this litigation had to submit their own

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ANDA for -- for their generic products?
A. So there must be something else that you're trying to get to here, but I -- I'm not sure why you would ask that question. I mean, obviously if you want to get approval, you've got to submit your ANDA to the FDA to get approval.
Q. So it's not important why I'm asking the question, I just need you to answer the question that was asked.
A. Well, I mean, it sounds reasonable what you're saying, but I may not be understanding fully what you're asking.
Q. You would agree that each separate manufacturer of a generic drug, including valsartan, has to submit its own ANDA for approval of its particular product. Correct?
A. That would sound to be reasonable.
Q. Okay. And each manufacturer would have to submit its own bioequivalence studies in support of its respective ANDA. Correct?
MR. DAVIS: I'm going to object to. This -- this is outside the scope. He's says he's not opining on bioequivalence data or he hasn't looked at that, it's not part of his report. I mean, every single answer he's given for the last

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ten minutes has been, "this is outside the scope." So I'd say move on if it's not in his report.
Q. Do you remember the question or did we --
A. I do --
Q. -- need to have it read back?
A. I do remember the question. Again -- again, I'm not opining on that. FDA could come back and ask for something else as part of the application review process, so I don't know.
Q. But you would agree that each ANDA applicant has to submit its own bioequivalence studies?
MR. DAVIS: Objection; asked and answered and he said it's outside the scope.
You can answer one more time.
A. So, as I said, it's not something I'm opining on. The FDA, when you make a submission to the FDA, they can come back and ask for additional information. So I -- it's possible they could ask for something else. I don't know.
Q. I understand you're referring to what FDA may or may not ask to in follow-up. But in submitting an ANDA initially, the respective applicant has to submit bioequivalence studies in support of that ANDA. Right?

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A. That sounds re- --
MR. DAVIS: Same objections.
You can answer.
THE WITNESS: Okay.
A. That sounds reasonable. Again, that's outside the scope of what I've looked at.
Q. All right. Let's take a look at Paragraph 16 of your report.
A. Okay.
Q. In this paragraph, which does have cer -- a number of subparagraphs, in this paragraph you refer to FDA reviewers. Correct?
A. I'm referring to the FDA fact sheet, which is where that information came from.
Q. But you do make reference in several places to FDA reviewers. Correct?
A. Well, let's see. I need to take a look at this.
Q. Just one example, if you look at Paragraph -- at Subparagraph C, about halfway down, there is a sentence starting with "FDA reviewers will study."
A. B? You're referring to B?
Q. No, C as in Charlie.
A. Oh, C. Okay.

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It does say, yes, FDA reviewers.
Q. Okay. And so when you refer to "FDA reviewers" in your report, is that what's also known as review chemists?
A. So, as I said before, what I'm referencing here is what FDA states in their fact sheet. Okay? That's -- I mean I'm just paraphrasing what FDA says. It could involve chemists.
Q. Okay. But --
A. It could involve others.
Q. You're stating this in your report, and I just want to get your understanding as to whether the term "FDA reviewers," as it appears there in Paragraph 16(c), whether that is what is also known as a review chemists.
MR. DAVIS: Objection; asked and answered. He has provided his understanding. He said "Could be chemists. Could be others." He answered it.
A. So I'll say the same thing again. It could include chemists. It could include others. It probably depends upon the application. It probably depends on who they want to have take a look at the particular file.

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Q. Does your term "FDA reviewers" include inspectors?
A. In the context here, this is referring to the FDA review process, which would typically not include -- and they -- I refer to "investigators." The FDA -- I wouldn't use the term "inspectors" with the FDA anyway. They're FDA investigators. This would not include that term.
Q. Okay.
A. You would never refer to an FDA investigator as an inspector.
Q. Okay. And reviewers would not actually accompany investigators in the field. Correct?
A. Not always. I think -- believe sometimes they have. That's -- that would not be typical.
Q. Okay. Reviewers will send requests to the Office of Regulatory Affairs at the time that an application is nearing approval. Right?
A. That's right.
Q. And that could be to arrange for CGMP compliance inspection of the applicant's manufacturing facilities?
A. So here is how this process works. It's not quite the way you described it.
Q. Okay.

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A. They will ask -- they will ask the office, "Is the firm in compliance" -- they'll ask three things, is the firm in compliance, have they had a recent inspection, does the firm require a preapproval inspection, or is the firm out of compliance?
And so, depending on what the answer is, that will be their action. If they have recently had an inspection that was a good inspection, they may not ask for a new preapproval inspection, they may rely on the old one.
If -- most likely, they will have a preapproval inspection. Or, if there is something out of compliance, they will say, "No, this should not be approved."
It depends upon the individual circumstance.
And if you notice, in a lot of the warning letters, the FDA makes the statement, future submissions will not -- basically, will not be approved, until the warning letter is resolved.
Q. Are you familiar with FDA's district laboratories?
A. I know they have laboratories. Okay? Have I been to one of the FDA district laboratories?

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No, I've not.
Q. And do those FDA district laboratories participate in essentially verifying that the information submitted to the FDA is accurate?
MR. DAVIS: Objection; vague.
You can answer.
A. So I'm not certain exactly what these laboratories would do in this review process. They may or may not do something. I don't know. They may not even choose to use these laboratories. I don't know. Probably depends upon the individual application.
Q. And would the activities of the FDA's district laboratories be outside the scope of your opinions, in your view?
A. Well, it is outside the scope, because I've not referenced them.
Q. And you're not going to be offering any opinions in this litigation that are outside the scope of your report. Right?
MR. DAVIS: Well, hang on. He has submitted this Declaration For a Class Certification. You said "this litigation." He may very well offer another expert report in this litigation, so I want to make that very clear.

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But, with that, you can answer.
THE WITNESS: Sure.
A. This is not a merits report. This is a declaration. So if I -- if there is additional reports, it may well extend beyond this.
Q. Are you intending to offer any opinions in this litigation with respect to the activities of district laboratories, FDA district laboratories?
A. Not as it pertains to this declaration.
Q. Are you going to opine in this litigation on the content of the ANDAs for valsartan or valsartan-containing products?
MR. DAVIS: Objection; calls for speculation. I'm not even sure how he can answer a question like that.
A. So I've not been asked to do anything beyond this declaration at this point in time, so the answer is I don't know.
Q. Are you going to offer any opinions with respect to what is required to be in ANDA?
MR. DAVIS: Same objection. And, again, another objection on this is that we're not required to disclose merits experts yet. So if that's what you're trying to do, is to get him to disclose himself as a merits expert, I object to

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that, and I would probably instruct him not to answer.
I don't think -- I don't see where you're going with asking about what he might hypothetically do in the future if we ask him. He doesn't know that.
Q. In connection -- withdrawn.
Are you going to offer any opinions with respect to whether the impurity profile of an ANDA drug has to be exactly the same as the impurity profile for a reference listed drug?
MR. DAVIS: Same objection.
And I think I'm going to instruct the witness not to answer it.
You're asking whether he might submit a report in the future that addresses something else, and we're not required to disclose experts yet on that. So, with that, I will -- I think I'm going to make an instruction.
So you don't have to answer that.
MS. ISIDRO: So --
MR. KERNER: You're instructing the witness, who is not your client, not to answer a question?
MR. DAVIS: Look, I mean, you know

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what, I'm going to withdraw the instruction, because I don't see what he could possibly say. Because he has no idea what -- he hasn't been asked to do anything like that, and it's -- this would call for pure and utter speculation on his part.
So I don't see where you're going with this question. I think it's an utter waste of time. You've asked the same question five times in a row now. His answer is going to be the same.
But you can answer one more time.
MS. ISIDRO: The record is clear that I have not asked the same question five times in a row.
And he has offered testimony that there are certain things that are beyond the scope of his opinions, and so we need to confirm that he won't be opining beyond the opinions that he has identified here today, absent proper disclosure in the litigation.
MR. DAVIS: But your question is whether he's going to do so in this litigation, and that's what I'm objecting to. So if you want to rephrase your question, you can rephrase it.
But as far as whether he's going to at some point in the future render a merits expert

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report that may address some or all of those topics or none of them, you know, that calls for wild speculation, and he has no idea of how to answer that. And we're not required to disclose our experts on that point.
MS. ISIDRO: Can we just read back the last question that was asked, and if there was any answer to it, let's get that answer read back.
MR. DAVIS: I'm going to make an attorney-work-product objection as well to all those prior questions.
(The requested material was read.)
A. So the answer, again, as I said before, is I don't know. I've not been asked to do anything beyond this declaration document that you have, so I don't know.
Q. Let's take a look at Paragraph 23 of your report.
A. Which one?
Q. Paragraph 23. And there is a reference about halfway through the paragraph, where you say: It is obvious that the regulations also take a much broader approach to their view of adulteration, including a manufacturer's compliance with CGMP, which might prevent products from becoming

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contaminated in the first instance.
Can you explain what you mean by "much broader approach to their view of adulteration"?
A. Well, the point I made earlier relative to adulterated product is the fact that CGMPs are not being met, the product would be considered to be adulterated.
If there was an example of adulteration of the other sort from a contamination standpoint, there might be a more in-depth review of CGMPs.
Q. And did this broader approach that you reference impact your opinion with respect to whether the presence of NDMA or NDEA in defendants' valsartan adulterated the valsartan products?
MR. DAVIS: Object to form.
A. So my opinions were based on the CGMPs that I've observed through the review of the documents.
Q. And when you say "through your review of the documents," are you referring to the documents that are listed on Exhibit A to your report?
A. I am.
Q. Okay. Is it your opinion that even a particular lot of valsartan that did not contain any detectable NDMA or NDEA was adulterated?

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MR. DAVIS: Objection; incomplete hypothetical.
You can answer.
A. So what I said before is that the product doesn't necessarily need to be adulterated to be considered to be adulterated -- I mean, contaminated to be considered adulterated if it's in violation of CGMPs.
If it's in violation of CGMPs, the products are considered to be adulterated.
Q. And when you say "if its in violation of CGMPs," does that "it" refer to the product?
A. It refers to the way -- the quality systems in the last spec in terms of CGMPs which involve a number of different things.
But if the firm is in violation of CGMPs, everything that they're making would be considered to be adulterated.
I think we went through that this morning.
Q. So to be clear, is it your opinion that if there was any CGMP violation anywhere in the firm, a particular lot of valsartan coming from that firm would be considered adulterated, even if it contained no detectable nitrosamines whatsoever?

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MR. DAVIS: Objection; incomplete hypothetical, asked and answered many times this morning.
You can answer again.
A. So I'll restate again what I said before, is that the position of the FDA is if the firm is not operating according to the CGMPs, the products that it's producing are considered to be adulterated, regardless as to whether they're contaminated or not.
Q. So I understand that your answer refers to the position of FDA. You're not here speaking for FDA today. Correct?
MR. DAVIS: He is speaking here about his interpretation of the FDA's regulations.
Q. My question was you're not here speaking for FDA today. Correct?
A. Of course I'm not here to speak for FDA.
Q. I didn't think it was a controversial question.
And my question to you for that reason was not what FDA's position is. My question to you was what is your opinion.
Is it your opinion that if a firm had a CGMP violation anywhere in the firm, even if it was

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completely unrelated to valsartan, a particular lot of valsartan coming from that firm would be considered adulterated even if it contained no detectable nitrosamines whatsoever?
MR. DAVIS: Objection; asked and answered again. Objection; incomplete hypothetical. Objection; relevance.
You can answer.
A. So I've answered your question before, but I'll answer it again. Okay?
As I said before, if the CGMPs are not being met, the products that are being produced, regardless of whether there is contamination or not, are considered to be adulterated.
Q. And that's your opinion?
A. Well -- so I base opinions on what the regulatory requirements are. I don't -- I don't -- as John Quick I don't dream up new regulations or new guidance. I don't do that. I follow what FDA says is the guidance and the regulation.
Q. And so I'll ask again, is that your opinion?
MR. DAVIS: Hang on. All these -- I'm restating all my objections, and he's clarified what his opinion is. Asked and answered again.

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Like what else do you want to hear?
A. What do you want -- what do you want to ask -- what do you want to hear again?
Q. Let's look at Paragraph 25 of your report, starting with the second sentence in that paragraph.
You state: For a facility to be in compliance with CGMP -- or, actually, let me rephrase that.
So looking at Paragraph 25, you have quotation marks around the bulk of the language in Paragraph 25. Correct?
A. I do, yes.
Q. And you don't have a specific citation going with those quotation marks, do you?
A. There is no footnote there.
Q. Okay. You attribute this language generally to the FD&C Act, but you don't specify where in the FD&C Act it comes from?
A. So it's probably one of the guidance documents like we reviewed this morning where that quote came. This is not a quote that I put together. It's a quote from the FDA, so -- or the -- or the act, so I'm not certain where that came from.

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Q. It's a quote from the act or from a guidance document?
A. Like I said, I'm not sure. It was one of the documents I reviewed. It may have been in another one of the documents I footnoted elsewhere. I just didn't put a footnote here.
Q. Okay. So focusing on the FD&C Act, Section 501 has to do with adulterated drugs and devices. Correct?
A. I'm not certain. I don't memorize these numbers.
Q. Does Section 502 have to do with misbranded drugs and devices?
A. Again we'll have to pull it up to look at that.
Q. As you sit here right now, without looking at it, you're not sure one way or the other?
A. Well, I've got like a hundred references here. And so if we're speaking to exactly what one of them specifically states, we need to pull it up and look at it and we can review it.
Q. No. My question was just does Section 502 of the FD&C Act have to do with misbranded drugs and devices?
A. Okay. We haven't looked at that, but

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I'll say okay.
Q. You'll say "okay" or do you know one way or the other?
A. So for me to sit here and tell you that specifically refers to that, without going back to the reference, I can't tell you.
Q. So you would have to look at Section 502 of the FD&C Act in order to know whether it deals with misbranded drugs and devices?
A. Right. Just to make sure I'm giving you a correct answer.
MR. DAVIS: Objection; mischaracterizes testimony.
(Discussion off the written record.)
MS. ISIDRO: Okay. So let's go ahead and mark this as Exhibit 12?
MR. DAVIS: I think -- 11, I think.
(Exhibit 11 was marked.)
Q. And we've marked as Exhibit 11 a copy of Sections 501 and 502 of the FD&C Act. And looking at Exhibit 11, can you now confirm that Section 501 of the FD&C Act has to do with adulterated drugs and devices?
A. I can.
Q. And can you now confirm that Section 502

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of the FD&C Act has to do with misbranded drugs and devices?
A. That's -- that is correct.
Q. And you can take as much time as you need to look through this, but is your quoted language from Paragraph 25, does it appear anywhere in Sections 501 or 502 of the FD&C Act?
MR. DAVIS: Do you want a moment to review the document?
A. Yes. Because like I said -- like I told you before, I'm not certain it came from this document, because I'm not sure where it came from. It may have come from another document like we reviewed this morning. But I'll be glad to look at this.
Q. As I said, feel free to look through it and just let me know one way or the other whether the language in Paragraph 25 comes from either of these sections in Exhibit 11.
A. (Pause.)
THE VIDEOGRAPHER: Off the record, 2:09 p.m.
(Break.)
THE VIDEOGRAPHER: Back on the record, 2:11 p m.

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Q. Mr. Quick, when we went off the record you were taking some time to look through Exhibit 11 to see whether the quote in Paragraph 25 came from either of the sections that are in Exhibit 11.
Did you have sufficient time to review? Do you need additional time?
A. I don't see that section in here. I didn't indicate it was here, so I'm not -- but I don't see it here, to answer your question.
Q. Okay.
MR. DAVIS: If you like, on the next break we can look for it and see what he's referring to and get back to you on that.
Q. All right. Focusing on the last sentence of Paragraph 25, that states that: A facility must have in place systems that ensure proper design, monitoring, and control of manufacturing processes and facilities.
Correct?
A. That's what the statement says.
Q. Does that refer to SOPs?
A. It probably refers to a number of different things. The systems -- the manufacturing system -- the manufacturing operation has got to be in control, and it talks about the processes and

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facilities, so part of that would be SOPs. But you've got to follow the SOPs.
Q. Did you review defendants' SOPs in forming your opinions in this litigation?
MR. DAVIS: Objection to the use of the word "this litigation."
A. So --
MR. DAVIS: You can answer.
A. -- I'm not sure whether any of these reference documents included SOPs or not. I know I've requested SOPs, but I'm not sure whether I reviewed those SOPs in the context of this declaration.
Q. As you sit here today, are you aware of whether any specific defendant had a quality policy in place?
MR. DAVIS: Objection; vague.
You can answer.
A. I'm not. I'm not quite sure what you're asking. No, I did not look at whether they had a quality policy or not.
Q. As you sit here today, are you aware of whether any defendant in this litigation had an SOP relating directly to quality?
A. Relating to what?

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Q. To quality.
A. I mean, quality is a large topic. What specific aspect of quality?
Q. Any aspect of quality.
A. Well, I'm sure that they have SOPs that refer to some aspect of quality. You'd almost have to have that. So, I mean -- I'm not sure -- your question really doesn't make any sense.
Q. In your answer there you're making an assumption, right, when you say "I'm sure that."
Am I interpreting that correctly? You're making an assumption that they would --
A. An assumption, yes.
Q. But you haven't specifically reviewed any SOP of any of the defendants relating to any aspect of quality?
A. No, I didn't say that. What I said was there may have been SOPs in the documents I reviewed. They're in the list here. There may have been SOPs in some of those documents. I'm just not -- I just don't recall that.
Q. Are you familiar with Section -- with 21 U.S. Section 352?
A. That number doesn't -- I don't recall exactly what that number would be referring to.

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Is that a document I referenced?
Q. Let's go ahead and mark a copy of 21 U.S.C. 352 as Exhibit 12.
MR. DAVIS: I think we already have that marked here in Exhibit 11.
MS. ISIDRO: We do?
MR. DAVIS: Yeah. Section 502 is 21 U.S.C. 352.
MS. ISIDRO: Let's go ahead and mark this copy anyway, Exhibit 12.
(Exhibit 12 was marked.)
Q. And 21 U.S.C. 352 deals with misbranded drugs and devices. Correct?
A. I didn't -- I didn't hear the question. Would you repeat it?
Q. 21 U.S.C. 352 deals with misbranded drugs and devices. Correct?
A. That's correct, yes.
Q. Does it -- does 21 U.S.C. 352 mention anything with respect to purity of a drug product?
A. If we want to spend the time to review this we can, but I don't recall.
Q. As you sit here today, you don't know one way or the other?
A. Well, it may. If you want me to read the

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document --
MR. DAVIS: Yeah. Why don't you take a few minutes to read the document.
A. (Pause.)
I don't see a reference to purity in this document.
Q. There's no reference to purity, there's no reference to impurities. Correct?
A. I didn't see that in the document, yes.
Q. FDA actually allows for the presence of some unidentified or unspecified impurities with a drug product below a certain threshold. Correct?
MR. DAVIS: Objection; vague, and incomplete question.
You can answer.
A. So that's not an area I was opining on, in terms of whether they allow or don't allow that. That may be the case, but that's not an area I was opining on.
Q. And so, as you sit here today, you can't speak to that one way or the other?
A. I can't speak to that. Right.
Q. The purity of an API product is shown on the certificate of analysis. Correct?
MR. DAVIS: Objection; vague, again.

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You can answer.
A. So certificate of analysis has a number of -- number of things that are reported on the certificate of analysis.
Q. And is purity of the API one of the things?
MR. DAVIS: Objection.
A. Well, typically it would be potency, other things in there. Purity is probably not something that would be on the C of A.
Q. You say "probably" does that --
A. I --
Q. You're not sure one way or the other?
A. I'm not sure.
Q. Okay. Are you aware whether at any time any valsartan products or valsartan-containing products were determined to be subpotent by the FDA?
A. I'm not aware of any situation. I mean, that doesn't mean it didn't happen, I'm just not aware of it.
Q. Now, labeling of allowable impurities or disclosing impurities in any amount on a marketed drug product label is not something that's required in an ANDA. Correct?
MR. DAVIS: Object to form.

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You can answer.
A. So I know where you're going to go with this. So the -- the --
Q. I'm going to ask you to not try and guess where I'm going with any question.
A. Okay.
Q. If you could just stick to answering --
A. I'm not --
Q. -- questions that are asked.
A. I'm not sure. I haven't looked at what actually is required on the labeling other than -- no.
Q. Okay. So do you know one way or the other whether labeling of product potency within allowable limits is required by FDA?
MR. DAVIS: Object to form.
You can answer.
A. If potency is what?
Q. Do you know one way or the other whether labeling of product potency within allowable limits is required by FDA?
A. Well, the potency would be on the labeling.
Q. And that is required by FDA. Right?
A. Well, again, that's not something I'm

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opining on but, yes, I would assume so.
Q. Okay. At any time did FDA require any manufacturer to change it -- its approved labeling to declare that NDMA or NDEA be listed as impurities on their a valsartan product labels?
A. I don't know.
Q. Mr. Quick, you're not taking the position that any manufacturer ever purposefully added NDMA or NDEA to their products as part of their formulation. Correct?
A. That they knowingly and purposely added, no, I'm not taking that position.
Q. Okay. And you're not offering any opinions on the content of any of the valsartan lab -- product labels. Correct?
A. Other than the fact that I made the comment that they're misbranded.
Q. Now, let's take a look at Paragraph 30 in your report.
A. Okay.
Q. You state in Paragraph 30 that: Because the presence of NDMA and/or NDEA was not revealed in the labeling, advertisements and/or patient booklets given to consumers at the time of dispensing, this also resulted in defendants' valsartan products

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being misbranded.
A. That's what it says.
Q. What is your basis for that statement?
A. Because it's different from what the branded product was, the Novartis product which did not have these contaminants.
Q. Do you know whether the branded product was ever tested for NDMA or NDEA prior to July of 2018?
A. Well, what I do know is that Novartis tested the ZHP product and found a contaminate in June of 2018.
Q. Do you know whether Novartis's product, Novartis's brand product, was ever tested for the presence of NDMA or NDEA prior to July of 2018?
A. I do not know.
THE WITNESS: Could we take like a five -- five-minute break?
MS. ISIDRO: Sure.
THE VIDEOGRAPHER: Off the record. The time is 2:27 p.m.
(Break.)
THE VIDEOGRAPHER: Back on the record. The time is 2:39 p.m.
Q. Mr. Quick, we've talked about CGMPs a bit

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today. Right?
A. We have.
Q. The C in CGMPs stands for "current." Right?
A. That's right.
Q. And that requires companies to use technologies and systems that are up-to-date at the current time. Right? The respective current time?
A. Well, current refers to current. So...
Q. Look, you say in your report: The C in CGMPs as standing for current, requiring companies to use technologies and systems that are --
A. Right.
Q. -- "up-to-date in order to comply with the regulations..."
A. Right. That's correct.
Q. And then, with respect to Paragraph 32, I believe you stated earlier that if pulling up any warning letter would be -- that basically any warning letter would provide support for that statement. Right?
A. Well, we also pulled up the other document from FDA that stated the same thing this morning, if you remember.
Q. Okay. But you had -- you had

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mentioned --
A. I did.
Q. -- warning letters?
A. Warning letters would typically have that. Maybe not all warning letters, but warning letters typically would.
(Reporter admonishment.)
Q. Do you recall receiving any warning letters from the FDA during your time at Baxter?
A. Yes.
MS. ISIDRO: Let's go ahead and mark as Exhibit 13, a August 11th, 2000, warning letter, CHI-29-00.
(Exhibit 13 was marked.)
Q. I'll give you a moment to take a look at Exhibit 13. But when you're ready, this is a warning letter that was sent to Baxter. Correct?
A. It was a warning letter sent to Baxter, yes.
Q. And this was during your time at Baxter?
A. That's correct.
Q. In fact, you're cc'd at the bottom of the warning letter. Correct?
A. That's correct.
Q. Do you recall receiving this letter?

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A. We're talking something that occurred 22 years ago. I don't -- no, I don't recall actually receiving it. I'm sure I did.
Q. And this letter discusses that: During in -- inspection conducted at one of Baxter's facilities, the investigators found serious deviations from the current good manufacturing practice regulations.
Correct?
A. Where -- where are you reading?
Q. In the first paragraph of the letter.
A. The first paragraph. Okay.
(Discussion off the written record.)
Q. I'm just giving you a moment to read. When you're ready to proceed, let me know.
A. (Pause.)
Okay.
Q. So you would agree that this letter discusses that during inspection conducted at one of Baxter's facilities, the investigators found a series of deviations from the current good manufacturing practice regulations?
A. That's what it says, yes.
Q. And, in fact, it says: They found serious deviations from the current good

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manufacturing practice regulations.
Correct?
A. That's what it says, yes.
Q. It goes on to enumerate a number of those deviations. Right?
A. It does.
Q. And it also says on the last page that: The CGMP deviations that are identified are not to be considered an all inclusive list of the deficiencies at the facility.
Right?
A. That's correct. That's what it says.
Q. Does the letter say anything about any and every product that Baxter made at the same time as -- as the observation that the investigators made were adulterated?
MR. DAVIS: Objection.
A. It does. First paragraph.
Q. Did you consider, at the time that you received this letter, that each and every product that was made at that facility during the time that these observations were in effect, were adulterated?
A. We assumed that this applied to all the products that were made at the facility, yes, we did.

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Q. Did the facility go on to, for example, recall all of the product that it had on the market at the time that had been manufactured at that facility?
A. Well, there's no recall. But to answer your question, we did consider all the products to be adulterated.
Q. Did it put a distribution hold on all product manufactured at the facility?
A. No, we did not.
Q. And so you didn't initiate a recall, and you didn't initiate in -- a distribution hold, yet you considered all product manufactured at that facility to be --
A. We --
Q. -- adulterated?
A. So we took this letter very seriously.
Q. So, again, my question was, you didn't initiate a recall, and you didn't initiate a distribution hold, yet you considered all of the product manufactured at that facility to be adulterated?
A. Under the context of this, yes.
Q. Would you agree that the impact of CGMP violations depends on the nature of those violations

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and the specific drugs involved?
MR. DAVIS: Objection to form, and incomplete hypothetical.
A. So I'm not quite sure I understand what you mean by the question.
Q. Would you agree with that statement?
A. Well, I don't understand the statement.
Q. Are you aware of whether FDA has ever said that the impact of CGMP violations depends on the nature of those violations and on the specific drugs involved?
A. I haven't seen that specific statement.
Q. Let's look at Paragraph 41 of your report.
A. 41?
Q. Uh-huh.
A. Okay.
Q. You state in Paragraph 41 that: The decisions of the quality function should never be overridden by higher levels of management.
Correct?
A. That's correct.
Q. When you say "quality function" there, are you referring to the quality unit?
A. I'm referring to the quality function.

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Q. Are you familiar with something that is called the "quality unit" and is referenced in 21 CFR 211?
A. Yes.
Q. Is that what you understand to be the quality function?
A. They would be one and the same.
Q. Okay.
A. So just to clarify that point.
Q. Uh-huh.
A. The intent is if the quality decision makes -- if the quality unit makes the decision, it should not be overridden by management for any reason, senior management. That's the intent of that statement. They should have total autonomy to make those decisions.
Q. Are you saying that there are no possibilities under which management might have to intervene in order to affirm the integrity of the corporate quality system?
MR. DAVIS: Objection; misrepresents the testimony.
A. That's not what I said.
Q. Well, let me make sure I understand.
You said that if the quality unit makes a

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decision, it should not be overridden by management, senior management for any reason. Correct?
A. That is correct, yes.
Q. What if senior management believes that it is necessary to override the quality unit's decision in order to affirm the integrity of the corporate quality system?
MR. DAVIS: Objection to form, and incomplete hypothetical.
You can answer.
A. Well, what you just said makes absolutely no sense.
Q. So it's your position that there is no possibility that senior management would ever need to intervene for legitimate reasons while also affirming the corporate quality system?
A. The last part of your statement just contradicts the first part, so let me clarify this. Okay?
Is that it's certainly acceptable for senior management to have a discussion with the quality unit about the decision, but they should not override that decision.
Q. Your statement requires an assumption that the quality unit or the quality functions'

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decisions are always right. Correct?
A. I'm saying that they are the final decision, they should be the final decision. What I'm saying, as I said before, it's perfectly acceptable for senior management to have a discussion with the quality unit, why did you make this decision, let's talk about it.
But at the end of the day, the quality unit should not be overridden by the decision.
Q. Under any circumstances?
A. Well, unless you've got a -- unless you've got a quality person that's totally incompetent and that's gone rogue, I mean, which if you've got that situation, you have got a much bigger problem in the company.
Q. And if you had that situation, would it be appropriate for senior management to intervene?
MR. DAVIS: Objection; incomplete hypothetical.
But you can answer.
THE WITNESS: Okay.
A. That is a crazy question, and the reason that it's crazy is because senior management should not have somebody in that position to begin with that's not going to make intelligent decisions. So

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it's a problem with senior management then.
Q. Well, you, yourself, said "unless you've got a quality person that's totally incompetent that's gone rogue. If you've got that situation, you've got a much bigger problem."
But if you've got that situation, should senior management intervene?
A. Well, if you have that situation, then management probably should intervene. You should probably have a new quality person there. But that should never have happened in the first place, because management should have been following what the quality function is doing, and they should have recognized that problem before then. So that's -- this situation should never occur.
Q. Once the problem -- if there is a problem, once that problem is recognized, senior management should intervene. Right?
A. No, that's not what I said.
Q. Are you saying that if senior management recognizes a problem, it should not intervene?
A. What I said was, the quality unit's decision should almost always be final.
Your hypothesis here is you've got a quality person that doesn't know what they're doing

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or is incompetent or the other thing. And my point is, if that's the case, the management of the company should have done something well before a problem ever occurred in the first place.
Q. You say "The quality unit's decision should almost always be final."
A. And that's correct.
Q. Almost always is not always. Right?
A. In the unlikely event as to what you said here, if you've got -- I mean, if quality function is often on a wild -- I mean, a rogue quality person who's making erroneous decisions, that person should not have been in that job in the first place, and that person should have been replaced by management is what I'm saying.
But the typical aspect would be the quality -- here's the real point, is that in a lot of companies, senior management will override quality's decision because of business considerations which should never be done.
It's okay to have a discussion with the quality head, but you don't want to override that quality unit's decision. That's the whole point here.
THE WITNESS: I'm sorry. Am I going

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too fast?
THE STENOGRAPHER: You're fine.
Q. All right. Let's go to Subheading 3 of your report, where you talk about: Comprehensive Quality Management System.
A. Okay.
Q. Still on Page 10.
A. Sure.
Q. At Paragraph 44, you discuss the topic of SOPs as an element that's essential to forming the core of a quality system. Correct?
A. Yes.
Q. And at the top of Page 11, still under Paragraph 44, you list some specific --
A. Pertinent examples.
Q. -- examples of SOPs that a company should have. Correct?
A. Among others, yes.
Q. Each individual manufacturer establishes its own SOPs. Correct?
A. They should.
Q. And so SOPs can and do vary from one manufacturer to another. Right?
MR. DAVIS: Objection; asked and answered earlier this morning.

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But you can answer it again.
A. Well, of course they're going to vary, because they're not all written by the same person, but they should all be compliant with the regulations and guidances.
Q. As you sit here today, do you know whether any of the defendants in this litigation had SOPs on risk management?
A. I believe that there were some, yes.
Q. Are you aware of whether all defendants had SOPs on risk management?
A. I'm not certain whether they did or not. They should have had those SOPs. Whether they actually had them, I'm not sure.
Q. As you sit here today, do you know one way or the other whether any particular defendant in this litigation had SOPs regarding incoming raw materials and release?
A. If they had incoming what?
Q. The second category at the top of Page 11.
A. Oh, okay. Okay.
Q. As you sit here today, do you know whether any defendant in this litigation had SOPs on incoming raw materials and release?

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A. I'm not certain, but they should have had these.
Q. As you sit here today, do you know one way or the other whether any defendant in this litigation had SOPs on deviations or nonconformances?
A. I'm not certain. But let me just interject here for a second. The real issue is whether they were following their own SOPs or not. That's the real issue.
Q. As you sit here today, do you know whether any defendant in this litigation had SOPs regarding out-of-specification results?
A. Again, same answer to the ones before, they should have had these SOPs. Whether they actually have them, I'm not certain. I mean, I know some of these probably did, because some of these are referenced at various places, but for me to tell you for all of the defendants whether they had all of these SOPs, I don't know whether they had all of these SOPs. My assumption is they probably did.
Q. Okay. And is your answer the same with respect to all of the categories that you list at the top of Page 11 --
A. Yes.

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Q. -- of your report?
A. So I'll add a comment to that, though. The real question in many cases is whether they were adequate or not.
Q. Would someone be able to determine an SOP's adequacy without reviewing it?
A. Without reviewing it?
Q. Uh-huh.
A. I mean, if you're going to determine it to not be adequate, you'd have to review it, I mean, or know the outcome, if it wasn't the right outcome. I...
Q. Let's go to Paragraph 46 of your report. You state in Paragraph 46 that: The number one citation by FDA year after year is the following, quote, procedures not in writing, comma, fully followed, end quote.
Right?
A. Right, that's what it says.
Q. And you cite to a specific website immediately following that. Is that the reference from which that quote comes?
A. Yes.
Q. And the website that's referenced there in that paragraph, Footnote 15, is that an

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inspection observations website?
A. What it is, it's a list -- it goes through 21 CFR 211, and it lists the number of times a firm has been cited for each of the areas, and the failure to follow procedures or not having had the procedures, it's always at the top of the list for the number of instances where there have been citations.
Q. Let's go ahead and mark as --
MR. DAVIS: 14.
Q. -- Exhibit 14 this web page with the title: Inspection Observations.
(Exhibit 14 was marked.)
Q. Reviewing the content of this exhibit, is this what you're referring to in Footnote 15?
A. I'm not certain. I'm looking at the bottom. It doesn't appear to be the same as the reference footnote.
Q. You are correct. The URL is not the same and I'll represent to you that when you type in the URL in Footnote 15 --
A. Okay.
Q. -- it automatically redirects to the footnote at the bottom of Exhibit 14.
MS. HILTON: I'll confirm.

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Q. So can you point me to where this quote appears in this inspection observations web page?
A. So in order to find that, you have to click on the link for the specific year and then it will detail out in order of occurrence the observations and what they were for.
Q. So your statement that the number one citation by FDA, year after year, is based on your review of the information that appears in each of those links for any given year?
A. So I did not go back and review every single year here, but historically -- and I review this periodically -- that it's typically the number one citation for failure to follow your own procedures.
Q. So that's based on your experience?
A. My experience. But, I mean, that's -- you can go to the website and you will see the number of occurrences and what they were for. And these are always at the top of the list, in terms of number of occurrences.
Q. Okay. Let's go to Paragraph 47 in your report.
A. Okay.
Q. In that paragraph you refer to two

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different warning letters. Correct?
A. I do.
Q. And these warning letters were issued to two different firms?
A. That's correct.
Q. Are you aware of whether either of those firms made or makes valsartan-containing products?
A. I don't believe. I don't know for certain, but I don't believe either one of these make valsartan.
Q. Okay. And do these -- do these warning letters have anything to do with nitrosamines at all?
A. As far as I know, they do not. That was not the intent of the reference.
Q. Okay. Are you aware whether either of the firms who received these warning letters that are referenced in Paragraph 47 manufactured solid oral dose products?
A. I'm not certain.
Q. Okay.
A. They may. I'm not certain. But that was not really the relevance to putting that in, in the first place. The relevance was the fact that they were cited for not using proper risk management.

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Q. Let's go to Section E of your report.
A. Section what?
Q. Section E, as in Edward.
A. Okay.
Q. At Paragraph 76, and continuing through Paragraph 95, your report recounts the type of inspections that FDA conducts, right, and the possible outcomes of those inspections?
A. I do.
Q. And it talks about what possible outcomes might ensue if the FDA were to conclude that an official action was indicated or an OAI status was indicated. Correct?
A. I do.
Q. Are you aware of whether any of the facilities that manufactured valsartan-containing products for the U.S. in the 2012 to the 2018 time period were ever formally classified as OAI by FDA?
A. Yes.
Q. Which ones?
A. Well, I know ZHP was. And there may be others, but I know ZHP was.
Q. In the time period from 2012 to July 2018?
A. The 2018 inspection was classified OAI.

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Q. When did that inspection occur? When in 2018?
A. It was the summer of 2018.
Q. Okay. Are you aware of any others?
A. There may be others. I'm not certain.
Q. As you sit here today, you're not aware of any others?
A. Well, I mean, it's not something I looked at and reviewed.
Q. So as you sit here today, you're not aware of any others?
A. That I can speak definitively to, yes, you're right. That doesn't mean there weren't any.
And I suspect that the warning letters -- typically a warning letter would not be issued unless there was an OAI inspection. And a number of these firms had warning letters.
Q. Are you speculating right now?
A. I'm just telling you, typically a warning letter would not be issued unless there was an OAI inspection. So a warning letter would not usually -- a warning letter would very seldom ever be issued for a VAI inspection.
Q. But, again, as you sit here today, you're not aware of that particular situation occurring

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with any defendant other than what you have identified?
A. It's not something I specifically reviewed.
Q. Okay. So you're not aware --
A. I -- okay.
MS. ISIDRO: Let's go ahead and take a five-minute break.
THE VIDEOGRAPHER: Off the record. The time is 3:10 p.m. 0
(Break.)
THE VIDEOGRAPHER: Back on the record. The time is 3:26 p.m.
Q. All right. Mr. Quick, let's turn to Section G of --
A. Section what?
Q. G as in girl, in your report.
(Discussion off the written record.)
Q. You state in Paragraph 101 --
(Discussion off the written record.)
Q. So, Mr. Quick, you state in Paragraph 101 that you have reviewed a set of documents related to defendants' noncompliance with CGMPs in order to determine whether these examples of noncompliance with CGMPs are the type that would impact and be

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common to every valsartan product purchased by the class members. Do you see that?
A. I see that.
Q. I'm going to ask you about a few different portions of that sentence.
When you say that you reviewed a set of documents related to defendants' noncompliance with CGMPs, what are you referring to?
A. I'm referring to examples of noncompliance with GMPs. It wasn't all exhaustive. There were examples.
Q. How did you determine which examples you would review?
A. Well, there is no specific determination. I went through all the defendants and I pulled out examples that I thought were representative of what I considered to be serious examples -- serious GMP situations.
Q. And the ones that you pulled out are the ones that are listed in your report?
A. They are.
Q. Okay. And in the second part of that sentence it says that you went through that exercise: In order to determine whether these examples of noncompliance with CGMPs are the type

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that would impact and be common to every valsartan product purchased by the class members.
What do you mean by that?
A. Well, I mean, we were talking about GMP situations, not like somebody not wearing a hairnet. Okay? That would not be what I would be talking about here. These would be something that would apply to everything.
Q. So is it your position that a purported noncompliance with respect to ZHP's API would impact a product that contained Mylan's API?
MR. DAVIS: Objection; mischaracterizes his report.
A. So when I refer -- for example, relative to ZHP and, for example, Teva purchasing ZHP, we were talking about all of the ZHP relative to Teva that would apply to all of the class relative to that situation.
Q. So it's your position that the examples that you've provided with respect to ZHP would impact any product that utilized ZHP's API?
A. Well, yes. But to answer the question you brought it out for, am I going back to say relative to -- and, for example, the situation of Teva and Mylan, I'm not referring back to Mylan,

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that's a separate thing. But for Teva and ZHP, all of that would apply to the class group.
Q. I'm not sure I understood that. Can you clarify what you mean?
A. So I'm not trying to -- I'm not trying to represent that an issue with Mylan or an issue with ZHP would apply to customers that -- a Mylan product. However, if they're being sold the same way and they're processed by Teva in the same way, it would apply to all of the class group.
Q. And so similarly, you're not taking the position that in observation with respect to or an alleged noncompliance with CGMPs by Teva would impact a different ANDA holder's product?
MR. DAVIS: Objection; incomplete hypothetical.
But you can answer.
A. Okay. So we're talking about Teva versus Torrent. If we're talking about that, okay, for example, I'm not trying to imply what Teva did or did not do would impact what Torrent did.
The point was these GMP violations apply to the whole class, in terms of -- and all the pills, everyone that received the product.
Q. All right. So let's take a look at

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Paragraphs 104 through 106 in your report.
A. Okay.
Q. And here you are discussing observations that were made by FDA in an establishment inspection report in August of 2018. Correct?
A. I am.
Q. This was the 2018 inspection that you were referencing earlier?
A. Yes.
Q. At the time that these observations were made, Teva had already initiated its product recall of valsartan-containing products which utilized ZHP's API. Right?
A. I'm not -- I'm not certain of the time frames.
Q. You don't know one way or the other whether that recall was issued on July 16th of 2018?
A. I'm not certain when the recall was actually initiated. I'm sure it's there someplace, I just don't recall.
Q. Okay. Do you know whether -- do you know whether FDA had any information about the presence of NDMA exceeding 100 parts per million in 150 lots of valsartan API from 2014 and 2015 prior to receiving ZHP's response to the FDA's DMF

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information request letter from August of 2018?
A. I'm not certain what information FDA had or didn't have. I'm aware of the document you're referring to.
Q. Okay. So you don't -- you don't know one way or the other whether that was known to FDA prior to that response in 2018?
A. So I -- it -- I'm not -- I'm not sure how -- what relevance it has but, no, I'm not.
Q. Okay. And do you know whether that information was known to any of the other defendants in this litigation prior to 2018?
MR. DAVIS: Object to form, and potentially calls for speculation.
But you can answer.
THE WITNESS: Okay.
A. I'm not aware of it, but they should have been aware. So if you look at Section 105, this -- this is the situation that caused the problem with ZHP, they made a critical change. They characterized it as critical, but when they made their submission to the FDA, they called it a minor change. And this goes back to 2011 and this is what the defendants that used the ZH products should have been aware of.

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Q. Beginning at Paragraph 129 and continuing through to Paragraph 143, you discuss certain -- or you make certain representations with respect to Mylan. Correct?
A. Right.
Q. You speak of risk assessments for recovered solvents going back to --
A. Which paragraph --
Q. -- 2014?
A. -- are you referring to --
MR. DAVIS: I believe that's 129.
THE WITNESS: Oh, 129.
Q. Yeah.
A. 129. Okay.
Q. And you reference that with respect to Unit 8. Correct?
A. It is. That's what I reference here, yes.
Q. But the 2020 EIR for Mylan cited these observations in the context of Unit 7. Correct?
MR. DAVIS: Objection; mischaracterizes the -- the document.
But you can answer.
A. So I'm not certain. So in terms of the linkage that you're trying to make, I'm not certain.

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We'd have to go back and look at the documents.
Q. Do you know whether at the time of this EIR, do you know one way or the other whether any particular defendant was purchasing valsartan API from Mylan?
A. I don't know the time frames of when they were purchasing.
MR. DAVIS: Which EIR are you referring to, for the record?
Q. The EIR that you're referencing in Paragraph 129.
MR. DAVIS: Is there --
THE WITNESS: Which --
MR. DAVIS: Is there a EIR that's being referenced at 129?
Q. You're discussing observations from an EIR in these paragraphs. Correct?
A. I didn't reference the EIR. I referenced -- I have other references relative to the statements that I made in 129.
Q. Do you know where those came from?
MR. DAVIS: Where -- objection; vague.
A. So they came from References 61, 62, and 63.

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Q. Okay. So let me just ask it this way. Are you aware of -- are you aware of a February 2020 EIR from Mylan?
A. February 2020?
Q. Yes.
A. I may be.
Q. Do you know whether any of the observations you discuss with respect to Mylan in your report come from that EIR?
A. If they do, I would have referenced them in the document here.
Q. But as you sit here right now, you can't specify which, if any, came from that EIR?
A. No, but I did -- I do reference where the statements came from. And references 68, 69, and 70 all were from the 2020 EIR.
Q. Okay. And do you know which, if any, of the defendants had currently active ANDAs for products containing valsartan at the time of that 2020 EIR?
MR. DAVIS: Objection; vague. Objection to the form.
You can answer.
A. So you're asking -- was the question -- maybe you want to rephrase the question?

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Q. Sure.
Do you know whether any of the defendants had withdrawn their ANDAs with respect to products containing valsartan at the time -- by the time of that February 2020 EIR?
A. I'm not certain whether they did or not.
MR. DAVIS: Same -- same objections.
THE WITNESS: I'm sorry.
Q. Okay. Let's go to the section, starts at the bottom of Page 28: Evidence common to the class of defendant Teva's noncompliance with CGMPs.
Do you see that section?
A. I see that section, yes.
Q. And are you aware that on June 20th of 2018, Teva was informed of the preference -- presence of a previously known impurity? Previously unknown impurity?
A. It's what?

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Q. As you sit here today, you don't know one way or the other?
A. No, I'm not certain. No. Like, I want to say again --
Q. Uh-huh.
A. -- the statements I have in this report are examples, okay, I didn't review everything, they're examples that it was a class that applied to all products, so I didn't review every possible area of concern.

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14 Q. Are you aware that Teva announced a
15 recall of certain named valsartan products made with
16 ZHP's API on or about July 16th of 2018?
17 MR. DAVIS: Object to form.
18 You can answer.
19 A. I'm not aware -- well, I probably have
20 seen that, but I'm not particularly aware of it. It
21 wasn't pertinent to my report.

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14 Q. Okay. Are you aware one way or the other
15 whether Teva announced a recall regarding specified
16 valsartan products containing Mylan's API on
17 November 25th of 2018?
18 MR. DAVIS: Object to form.
19 You can answer.
20 A. The same answer as before. Again, there
21 were a lot of documents around that period of time
22 that I may have seen, but they were not relevant to
23 my report.

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Q. Did you review the reports of audits conducted by Teva at ZHP?
A. Yes. I think I referenced these in here as well.
Q. Did you ensure that you had reviewed the report of each and every audit that Teva performed at ZHP?
A. I don't know that I have reviewed every audit.
MR. DAVIS: Objection; outside the scope.
And you can answer.
A. I mean, I reviewed enough to see that there were deficiencies in the way that the audits were conducted.

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Q. Are you aware that Teva had risk-management SOPs in place in the relevant time periods?
A. Yes. And I believe some of those documents I've referenced.
Q. And those risk-management SOPs were called upon to manage the customer-API supplier relationships with ZHP and Mylan. Correct?
A. I'm not sure that characterizes it correctly, but...
Q. Okay. What's incorrect about that characterization?
A. Well, I -- I'm not -- I'm not certain, because I didn't look at it in that light. But if you're asking the question was I aware that there -- that Teva had risk-management processes in place, yes.

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[redacted]
MR. DAVIS: Object -- I'm going to object to the form.
You can answer.
A. They did, but they didn't get the information that they needed.
Q. And these inspections were made according to schedules established for audits of API suppliers. Correct?
A. Well, I don't know that to be the case. I don't know.
Q. You don't know one way or the other?
A. I don't know -- I don't know what -- you're asking the question whether they scheduled the audits. I don't know.
But the issue, though, is they failed to uncover the issues that existed.
[redacted]
Q. When you say "if it's here," you mean in your report?
A. Yeah, in the report, yeah.

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Q. Do you know one way or another if it's there?
A. I don't recall. I'd have to -- we'd have to go back and look at all the references.
But the point is, if they had done the audit the way I had suggested in 2011, they should have been able to determine this critical change and have investigated it.
Q. Are you aware of what a DMF is, a drug --
A. Yes.
Q. What do you understand DMF to refer to?
A. It's a Drug Master File.
Q. And what is a Drug Master File?
A. Drug Master File typically contains all of the aspects relative to making whatever it is, and it's by reference. And the ANDA or NDA will reference the DMF as a reference. So if the FDA does not approve a DMF, they'll approve the file that references the DMF.
Q. Okay. What entity holds the DMF?
A. What do you mean, "what entity"?
Q. Would that be the entity that supplies the API?
A. Well, the API manufacturer probably has DMFs. I'm assuming Teva probably had DMFs.

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Q. You're referring, in your response, to the ANDA will reference the DMF. What do you mean there?
A. Okay. So when you're going to the chemistry manufacturing control section of your ANDA or NDA, you'll reference the DMF. And, typically, that's what you would do. You don't actually include that as part of the ANDA or the NDA because it's by reference.
Q. Okay. So, for example, if a company like Teva is obtaining API from a company like ZHP, Teva's ANDA for the product that incorporates that API would reference ZHP's DMF for that API. Correct?
A. Well, so I'm not -- so Teva's got -- I mean, ZHP has their own file, they have a DMF that references their own file. So I'm not certain whether the Teva ANDA would reference necessarily the ZHP DMF. I don't know. I don't know whether that would be the case or not, because I'm assuming that Teva has their own DMF.
[redacted]

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[redacted]

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Q. Are you aware that DMFs are confidential?
A. Well --
MR. DAVIS: Object to form.
You can answer.
A. Well, confidential in the fact that the FDA is not going to release the DMF, if that's what you're saying. But the FDA is not going to release the DMF to anybody. But, I mean, ZHP could release it to whoever they want to.
Q. Is ZHP required by FDA to release it to anyone?
A. No, they're not required.
Q. Okay. And does FDA require ANDA holders to obtain access to these confidential DMFs?
MR. DAVIS: Object to form.
A. Well, as I stated, Teva probably has their own DMF, okay, which Teva would file as part of their filings. Okay? So ZHP would have their DMF. So I doubt seriously if Teva's filing had the ZHP DMF as part of it.
MR. DAVIS: Let me caution you not to speculate.
THE WITNESS: Okay. You're right.

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A. Okay. I don't know. But you're asking about if the FDA required it. I think that was the question?
Q. Is it your position that FDA would require any manufacturer of finished product that incorporates ZHP's valsartan API to get access to ZHP's DMF for that API?
MR. DAVIS: Object to form.
A. That's not necessarily a requirement. The real point, though, is that Teva should have understand -- understood the process that ZHP was following, either by getting access to the DMF or by getting the information when they came on their audits.

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(Discussion off the written record.)

MS. ISIDRO: Let's go off the record a moment.

THE VIDEOGRAPHER: Off the record at 4:05 p.m.

(Break.)

THE VIDEOGRAPHER: This marks the

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beginning of Media Unit 3. Back on the record. The time is 4:23 p m.

Q. Mr. Quick, I just want to make sure I understand your testimony. It's your understanding that ZHP had a DMF for valsartan API. Correct?

A. I believe that they did. Either that or they put it into their ANDA. So either one. They either had DMF or they had an ANDA. They had some sort of filing with the FDA.

Q. Okay. And it's your understanding that Teva had its own DMF for its valsartan ANDA?

A. No, I didn't say that. I said I assume that Teva most likely would have had their own DMF to make the drug product. That's typically what a pharmaceutical company would do. It's not a requirement to have a DMF, so they may or may not have had a DMF.

Q. So you're saying that Teva may have had its own DMF for its finished drug product, for its valsartan?

A. Yeah, for its drug product, yes. Again, it's not a requirement by the FDA, but most drug companies would do that.

Q. Okay. Did you review the quality agreement for active pharmaceutical ingredients that

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was in place between Teva by way of Actavis and ZHP?

A. I'm not certain whether I saw that or not.

Q. Okay. So as you sit here today, you're not aware, one way or the other, whether it requires that ZHP notify Teva/Actavis in writing upon the receipt of a regulatory inspection report?

A. So to answer that question, if there was a quality agreement in place, that quality agreement certainly should have spelled that out, okay, that ZHP was required to do that. That would be a normal component in a quality agreement between the two entities.

Q. You didn't check for that, did you?

A. I don't think I saw it, but I'm saying in that agreement, that's what they probably should have had. I mean, it's a basic requirement for a quality agreement.

Q. Okay. And as you sit here today, you don't know, one way or the other, whether that was in the quality agreement between Teva, Actavis, and ZHP?

A. No.

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Page 200

15 Q. But you didn't review that agreement?
16 A. Well, I didn't review it, but relative to
17 this it doesn't really matter because they should
18 have had it in the quality agreement, whether I
19 reviewed it or not.
20 Q. Right. But you don't know whether it was
21 in the quality agreement?
22 A. I don't. I don't know whether it was
23 there or not.
24 Q. Okay.
25 A. Right.

Page 201

1 Q. So it could have been, you just don't
2 know?
3 A. That's right. It could have been. But
4 if it had been there, then they should have notified
5 them.


Page 202
Page 204
Page 203
Page 205

Page 206

[redacted]

Page 207

[redacted]

Page 208

[redacted]

Q. Do you know whether Teva had any valsartan product on the market at this time in August of 2018?

A. I don't know, but it's not relevant to -- to the report that I had. And, again, as I indicated, my report addresses the CGMP compliant issues that were applicable to the entire class and it's not -- I -- it's not exhaustive, and if I had

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more documents I might include those in an updated report if we were ever to have such one.

Q. Would you agree that if Teva did not have product on the market in August of 2018, no decision that was made or not made in August of 2018 could have impacted product received by class members?

MR. DAVIS: Object to form, improper hypothetical.

A. So your -- your statement is an incorrect statement because there's obviously -- I don't -- I don't know what the expiration date is on the valsartan. So clearly there'd been product distributed prior to that time, probably within still expiration date, I don't know. So I -- I think -- I don't -- I think your statement is incorrect.

MR. DAVIS: I'd caution you not to speculate again.

THE WITNESS: Okay.

Q. Would that be nonrecalled product that you're referencing?

MR. DAVIS: I'd caution the witness not the speculate.

THE WITNESS: Okay.

A. I don't -- I don't know. But my point

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is, it's not really relevant. That's really what I intended to say.
Q. So it's not really relevant to you whether there was any product on the market that could've reached class members in August of 2018?
[redacted]
Q. Let's take a look at Paragraph 150 of your report?
A. 152?
Q. 150.
A. 150. Okay.
[redacted]

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[redacted]

Page 212

[redacted]
Q. The most serious level of observation which Teva auditors could make during an audit is a critical observation. Correct?
A. I don't -- I don't know whether that's what's in the Teva -- Teva procedure or not. I'm not certain.
Q. So you don't know how Teva defined a serious observation?
A. They talked about major and minor, so --
Q. Excuse me. You don't know how Teva defined a major observation?
A. It may have been in some of the documents I've seen, but I just don't recall.
Q. And you don't know how Teva defined a minor observation?
A. I'm sorry. I just don't recall if I had seen it. I may have seen it. I just don't recall.
[redacted]

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[redacted]

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Q. Would it be fair to say that the actions that you undertook to determine whether Teva's reaction to the major and minor observations was sufficient was to review the documents that you have identified in Exhibit A to your report?

MR. DAVIS: Object to form.

A. So I'm not sure which documents I review there.

Q. But the documents that you reviewed in connection with your report -- the documents that you relied on in connection with your report are listed in Exhibit A to your report?

A. That is correct.

[redacted]

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[redacted]

215

[redacted]

Page 217

[redacted]


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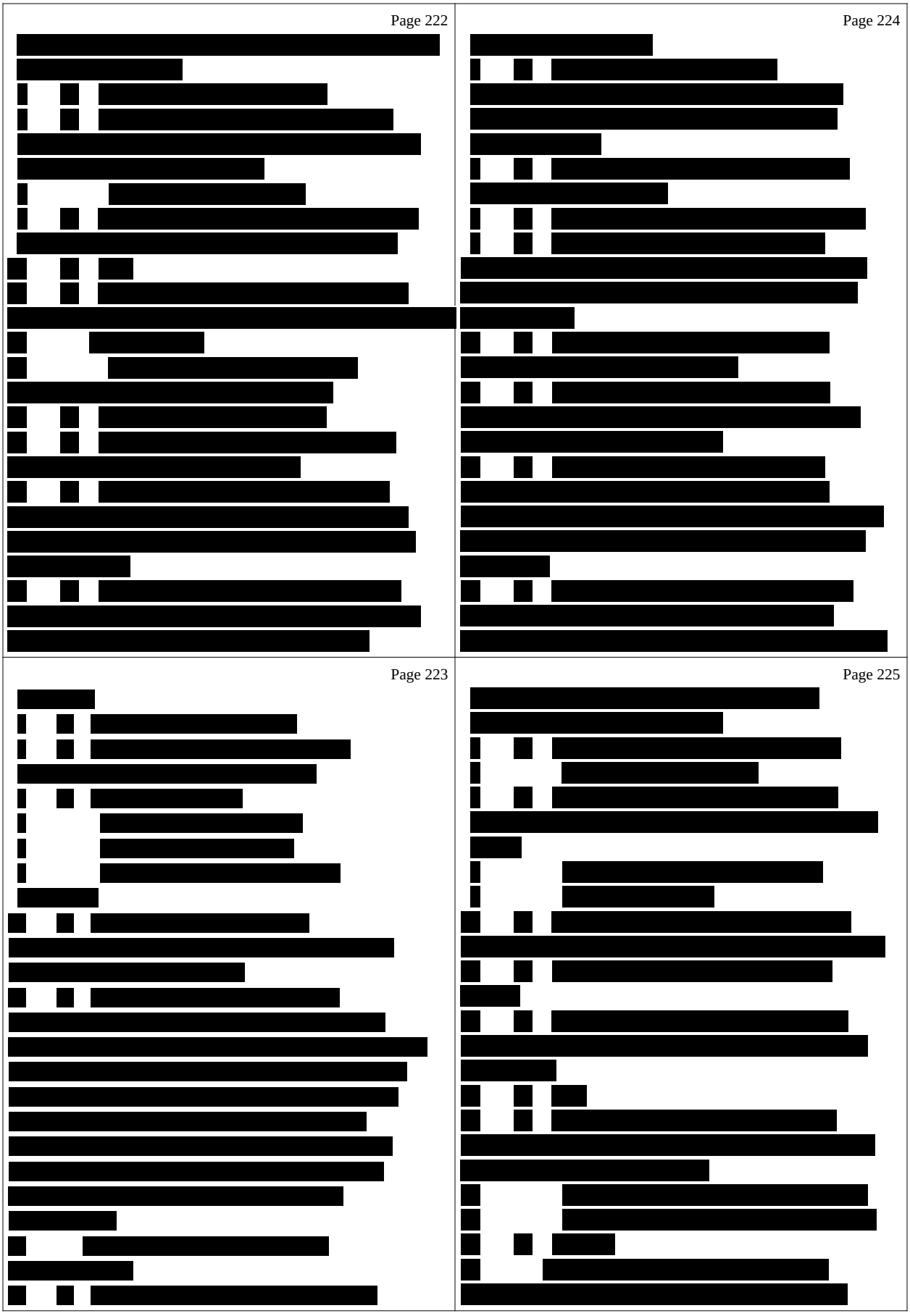
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12 Q. Okay.
13 (Reporter admonishment.)


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20 Q. You've commented on comprehensive quality
21 management systems. Correct?
22 A. Where are you referring?
23 Q. Is that something that you recall
24 commenting on?
25 A. I may have. Can -- what section are you

1 looking at?
2 Q. I'm not looking at a particular section
3 right now.
4 Is that something that you recall
5 commenting on?
6 A. I may have -- I may have commented on a
7 general way, at the beginning. There may be other
8 areas. You want to refer me to a certain aspect of
9 the report, I'd be glad to comment on it.
10 Q. I'm going to reference you to Page 10 of
11 your report. Do you see heading Roman Numeral III?
12 A. Yes.
13 Q. Competitiveness quality management
14 system?
15 A. Right.
16 Q. Do you see Roman Numeral II above at the
17 top of the page, it says: Responsible and trained
18 quality department?
19 A. I do.
20 Q. Was there anything that you saw in any of
21 the documents that you reviewed that implies that
22 Teva does not have an adequately --
23 (Brief interruption.)
24 MR. DAVIS: Let's go off the record.
25 MS. ISIDRO: Yeah. Off the record.

1 THE VIDEOGRAPHER: We're off the
2 record at 5:43 p.m.
3 (Break.)
4 THE VIDEOGRAPHER: We're back on the
5 record at 5:48 p.m. 0

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[redacted]

Q. So as you sit here today, you can't identify anything that implies that Teva does not adequate -- did not adequately conduct risk assessments per Q9, as you have described them?

A. Because I've not necessarily looked at all the appropriate documents that I could have looked at.

Q. Okay. And you have commented on change management systems in your Paragraph 49. Correct?

A. 49?

Yes.

Q. Was there anything that you saw in any

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documents that you reviewed that implies that Teva does not have an adequate change management system, as you have described it?

A. Again, I did not review that specific aspect of Teva to be able to make that determination.

Q. Okay. And you have commented on process validation at your Paragraph 57. Correct?

A. Yes.

[redacted]

Q. Okay. Anything else as to Teva with respect to process validation?

A. Nothing. But that was just one example. There could be more examples, if I had other documents to review.

Q. So if there are any other examples, it's not something that you reviewed?

A. I just didn't review it, yes.

Q. Okay. Okay.

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MS. ISIDRO: All right. I have no further questions at this time, and I'll pass the witness to the next questioner.

(Discussion off the written record.)

THE VIDEOGRAPHER: Go off the record.

(Break.)

THE VIDEOGRAPHER: Back on the record. The time is 5:54 p.m. Back on the record.

EXAMINATION

BY MR. GOLDBERG:

Q. Okay. Mr. Quick, my name is Seth Goldberg. I'm with the law firm Duane Morris, and we represent ZHP and a few of its affiliated companies.

I'm going to ask you a few questions about your report, and in particular the ZHP section of your report, which starts on Page 20.

MR. GOLDBERG: And I wanted to put up Exhibit -- well, make sure for the -- for the tech, this is Document No. 001 in our selection of documents.

Q. And while he's doing that, Mr. Quick, is it -- when you look at this section of the ZHP section, is it fair to say that you --

MR. DAVIS: We might have an issue

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here. Are you going to be able to read that, John?

THE WITNESS: I cannot read it.

(Discussion off the written record.)

(Exhibit 19 was marked.)

Q. This is the 2018 EIR report. Are you familiar with this document?

A. This is the ZHP?

Q. Correct.

A. Okay.

Q. Okay. You cite to this document a number of times in this section of the ZHP your opinions regarding ZHP. Do you see that? Why don't you flip through your report.

A. I see that.

Q. And most of your footnote cites refer to this document.

MR. DAVIS: Objection.

Q. Do you see that?

A. Yes, I do see that. Some of them do, you're correct.

Q. Okay. What do you understand this document to be?

A. This is the Establishment and Inspection Report written by the FDA investigator that inspected the ZHP facility in 2018.

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Q. And this document, if you look at the very back, it's signed and dated -- this is on Page 974, 58 of 58 in the PDF -- it was signed and dated by two investigators on August 20th, 2018. Do you see that?
A. I see that.
Q. Okay. Did you review any ZHP communications with the FDA dated after August 20th, 2018?
A. I may have. I don't recall.
Q. Well, I don't see any cited in your report, so did you or didn't you?
A. If it's not cited in my report, I didn't.
Q. Okay. What's a "warning letter closeout"?
A. Warning letter closeout would be when the FDA has reviewed whatever has been done relative to the warning letter to begin, they close out the warning letter.
Q. Did you review the warning letter closeout that the FDA issued for ZHP related to this EIR?
A. I may have seen that.
Q. Well, I just asked you if you looked at any document after August 20th, 2018, and you said

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you didn't.
A. No, I didn't --
MR. DAVIS: Well, hang on. Hang on, Mr. Goldberg. You asked if he reviewed any communications with FDA after 2018.
MR. GOLDBERG: Yeah, so --
MR. DAVIS: I'm not sure a warning letter -- a warning letter closeout would qualify.
MR. GOLDBERG: Well --
A. I'll tell you what I said. I'll tell you what I said, is that I may have reviewed some documents. I didn't refer to those documents in my report.
(Discussion off the written record.)
Q. Document No. 16. Do you know what this document is, sir?
A. I'm reading it.
(Pause.)
It appears to be the closeout to the warning letter.
Q. Is this the first time you've seen this document?
A. As I said before, I may have seen it at some point. I'm not sure whether I saw it or not.
Q. Yes or no, is this the first time you saw

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the document?
A. I answered your question. I said --
MR. DAVIS: Asked and answered.
Q. Why didn't you include it in your report?
A. It wasn't relevant to my report.
MR. DAVIS: Also, it was issued three days before he signed his report.
(Exhibit 20 was marked.)
Q. Why wouldn't the FDA closeout letter be relevant to your report?
A. What I cited in my report were examples of CGMP deficiencies that occurred during the period that I reviewed, and this occurred years after.
MR. DAVIS: Hey, Seth, I'm noticing there is not a Bates stamp on this document. Is this a document that ZHP has produced in this case?
(No audible response.)
Q. Did you review any of the observation responses, the specific observation responses that ZHP provided to the FDA in connection with this EIR?
A. The same applies to this. I may have seen some of those documents. There were a lot of documents that were provided. This document -- those documents are not relevant to what my report was about.

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Q. When you say "there were a lot of documents provided," could you give us a sense? What does that mean? Who provided them? What are you talking about?
MR. DAVIS: Hang on, Seth. Objection; asked and answered. This is -- this was covered at length this morning. I don't think each defendant gets a bite at the same apple when it's already been covered once.
MR. GOLDBERG: This wasn't covered this morning.
MR. DAVIS: It was. It was, Seth. It was covered this morning.
MR. GOLDBERG: I'm not going to waste time.
Q. Which ZHP documents, other than the ones you've identified in Exhibit A, were provided?
A. The documents that I reviewed are the ones that are in the -- in my report.
Q. Okay. So you didn't review the closeout letter, because that wasn't in your report. Right?
MR. DAVIS: Well, hang on, Seth. I asked you a question.
MR. GOLDBERG: No, no, no.
MR. DAVIS: Has ZHP produced this

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document?

MR. GOLDBERG: Excuse me. Counsel, Counsel, the witness just answered a question, and I'm following up on that particular answer. That's it. There is no reason for you to be speaking.

MR. DAVIS: Okay. You can answer the question, Mr. Quick.

A. I did not review this document relative to my report.

Q. And you didn't review any of the other communications ZHP had with the FDA between the date of the EIR and the closeout letter, because if you had, you would have identified them in your report. Right?

A. I would have -- that's correct, I would have identified them.

Q. Looking at Paragraph 105 of your report -- I'm sorry -- 104 of your report. You say that: The FDA observed that ZHP failed to conduct a formal risk assessment.

MR. GOLDBERG: You could pull that document down that's up there.

MR. DAVIS: I'm going to -- now that you've pulled it down, to the extent that's not been

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produced to us, I would request that be produced with a Bates stamp.

Q. Sir, did you -- do you need me to repeat my question or --

A. What was the question, please?

Q. -- maybe I interrupted. So let me turn your attention to 104. You say: The FDA observed that ZHP failed to conduct a formal risk assessment for the at-issue valsartan API manufacturing change. Do you see that?

A. I see it.

Q. Okay. And you cite to the 2018 EIR that we looked at. Right?

A. That's correct.

Q. Did you do anything to independently assess whether ZHP conducted a formal risk assessment, or are you just taking what the FDA is saying and putting that into your report?

A. I reviewed the documents that were provided. I reviewed the FDA EIR. Obviously, I was not on-site at ZHP to verify any of these documents, and so that's where this -- that's where this came from.

Q. Which documents? You said you "reviewed the documents provided," and I just want to be

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clear. You only reviewed what's on Exhibit A. Right?

A. That's correct.

Q. Okay. So did you do -- did anything in Exhibit A -- if you look at that list, did you do anything to independently verify whether ZHP conducted a formal risk assessment?

MR. DAVIS: Object to form.

You can answer.

A. So my role was to come up -- was to identify example -- examples of CH -- of CGMP deficiencies that might apply to the entire class, and not -- it was not exhaustive.

That may be part of a later scope in this process, but that's -- I did not do an independent review of any other aspects of the ZHP EIR.

Q. Okay. So the answer to my question is, no, you didn't do any independent assessment of whether or not ZHP did a formal risk assessment. Right?

MR. DAVIS: Objection. He's already given his answer.

Q. Sir, are you going to answer my question?

A. The answer --

Q. The answer is no.

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A. I told you no before.

Q. Okay. Where in the FDA regulations is the phrase "formal risk assessment" defined?

A. So I address that in my report. There are numerous places.

(Pause.)

So FDA addresses this in Q9. They also address it in the guidance "Control of Nitrosamine Impurities in Human Drugs." And I reference that as Footnote 17. And they've addressed very specifically the amount of risk assessment.

And if you look at my Page 11, you will see that. Risk assessments assess the risk in marketed products and products under approved and pending applications. Risk assessments should be conducted in a timely manner based on the prioritization of drugs. Manufacturers do not need to submit risk assessment documents to the agency, but they should retain these documents so they are -- should be available if requested.

So that's where FDA cites this.

Q. Does the FDA define with specificity the requirements of a risk assessment?

A. They may. I'm just not aware offhand where that might be.

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Q. The information you cited are not specific requirements of a risk assessment. Right?
MR. DAVIS: Objection.
A. So what -- what are you referring to?
Q. Let me ask a different question. Can we pull up Exhibit Document No. 17.
MR. DAVIS: For the record, this is Exhibit 21. Is that right?
MR. GOLDBERG: Correct. This should be Exhibit 21.
(Exhibit 21 was marked.)
Q. Do you see what the document is, sir?
A. I do. I do.
Q. What is the document?
A. It's quality risk management, Q9.
Q. And this is the document you just referred to a minute ago when you said the FDA talks about risk assessment in Q9. Right?
A. That's right.
Q. Okay. Could you turn to Page 6 of this document?
A. I don't have the document in front of me.
MR. DAVIS: Yeah, you're going to have to hand control over to him.
I'm going to place just a procedural

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objection on the record that he's not even able to review the entire document when it's presented to him.
Q. Sir, I'm turning your attention to Page 6 of Q9, which is a document you just referenced. And, actually, if you look at the bottom of Page 5, if you could turn to that, you'll see it says: Risk management methodology.
And why don't you take a second to review paragraph -- this section, risk management methodology, if you need to.
A. (Pause.)
Okay.
Q. Okay. And if you look at Page 6 -- and I'll just read this in the second paragraph. It says --
MR. DAVIS: Can you enhance the image so that he can actually see it?
MR. GOLDBERG: Again, I'm not -- I can't -- maybe the tech can.
MR. NOVAK: You just have to tell me what you're reading, so I know what you're reading from.
Q. It's a sentence that says: Below is a nonexhaustive list of some of these tools.

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Do you see that?
A. I see that.
Q. Okay. And then if you go past that list, it says: It might be appropriate to adapt these tools for use in specific areas pertaining to drug substance and drug product quality.
It goes on to say: Combined use provides flexibility that can facilitate the application and quality of risk management principals. The degree of rigor and formality of quality risk assessment should reflect available knowledge and be commensurate with the complexity and/or criticality of the issue to be addressed.
You agree that the FDA does not restrict to a specific list of components how a risk assessment should be conducted?
MR. DAVIS: Object to form.
You can answer.
A. That's generally correct.
Q. And that the FDA envisions that there needs to be some flexibility in this process and that it may be done in different ways depending on the circumstances?
MR. DAVIS: Object to form.
You can answer.

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A. It can be done in different forms.
Q. This document doesn't refer to a defined, quote, formal risk assessment, does it?
A. Well, I haven't read the entire -- if you want me to spend the time to read the document, I would.
Q. Well, this Section 5 does not. Correct?
MR. DAVIS: Again, I'm going to state my procedural objection that you're not even giving him the opportunity to look at anything other than what you've highlighted.
Q. Do you agree?
A. Based on what I'm seeing here, yes.
Q. Okay. What is your support for the conclusion that ZHP did not file -- follow its own standard management procedure?
MR. DAVIS: Object to form.
You can answer.
A. So we need to pull up Footnote 40.
(Exhibit 22 was marked.)
Q. Document No. 3. That's Footnote -- that's the document at Footnote 40, sir.
Do you want to show me what you're claiming is the support that ZHP did not follow its own SMP?

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MR. DAVIS: I object to that, Seth. He's not even able to control the document to show you.
Q. Well, your footnote says Page 11 of 17.
A. Oh, 11, yes.
(Discussion off the written record.)
MR. DAVIS: For the record, counsel has highlighted the top two paragraphs, it appears, of Page 11 of this document.
Why don't you let counsel know when you've read that and then you want counsel to highlight the bottom portion of the document next.
A. Yeah, why don't you highlight? Go ahead. You can move on.
(Pause.)
This appears to be a different version of the document than I have seen.
Q. Sir, this is the document you cited, ZHP0000417.
A. I'm just saying it appears to be --
Q. It goes on to --
(Simultaneous speaking.)
A. I'm just saying it appears to be a different document.
Q. You're not seeing support for your

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conclusion on this page. Right?
MR. DAVIS: Object in the way it's presented to the witness in piecemeal fashion, where he's not even able to read the entire page in one read. If you want, we can go off the record. I can print that document and we can start with it.
Q. Am I correct, sir, that you're not seeing on Page 11 the support for this opinion?
A. Well, we need to look at it as what they actually did. And I think the issue was what they actually did was simply checking boxes. And I think the FDA referenced that in the EIR. And I also saw that particular risk assessment document and I agreed with them.
Q. So the answer to my -- to my question is, yes, this doesn't support your conclusion?
MR. DAVIS: Objection; totally mischaracterizes his testimony.
A. That's not what I said.
Q. I asked you, am I correct that Page 11 doesn't support the language in Paragraph 108 that you're citing?
MR. DAVIS: Objection; mischaracterizes his testimony, and asked and answered now.

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A. This document needs to be reviewed in the context of what ZHP actually did. And what they actually did was do a series of check the boxes, which I saw that document. If we look at that document, you would see it. And the FDA also referenced that in their inspection when they were at ZHP and it's referenced in the 2018 EIR.
Q. Did you review ZHP's response to that particular part of the EIR?
A. We've already been through that and I told you I did not review the responses.
This is in the total context of --
MR. DAVIS: There's no question pending.
Q. Other than what the FDA said in the EIR, did you review any particular document that supports this conclusion at Paragraph 108 --
A. As I said --
Q. -- in your report?
A. -- as I said, I reviewed the actual risk assessment document that they actually did, which the FDA cited. I reviewed that document. It is a series of check the boxes.
(Reporter admonishment.)
Q. Document No. 2 in our list. 2A is the

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translation of this document.
THE STENOGRAPHER: And don't forget to give these exhibit numbers if you want to mark them. I won't mention this again, but just for the record. Thanks.
Q. We can mark this as Exhibit 23. I'm showing you the change request form document.
(Exhibit 23 was marked.)
Q. When you say this was a "check the box," what do you mean by that?
MR. DAVIS: For the record, the witness -- the type font in here is like 6.
I object to this procedure of doing this. Like you're asking him very specific questions about documents and not letting him actually look at the document.
MR. GOLDBERG: Don't you have the electronic version of the document? Isn't that how this works?
MR. DAVIS: Well, look, I can't pull it up right on command, Seth.
(Simultaneous speaking.)
MR. GOLDBERG: You can access the electronic version of the document.
MR. DAVIS: I don't know what

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exhibits you're going to mark.
MR. GOLDBERG: Well, no, but when the court reporter puts them up, Mr. Quick should be able to review them.
MR. DAVIS: Yeah. He's looking --
MR. GOLDBERG: That's how we've done that in the past.
MR. DAVIS: Well, let me explain to you, Seth. He's about 30 feet away from the TV and he's looking on an iPad. And unless you blow up the document, he can't read the text. I can't read the text. And he's not able to page through the document to actually give it a good review. You're just, you know, highlighting the portions you want to show him. I think this is an improper procedure for doing this.
MR. GOLDBERG: Well, these are documents that he relied on to issue his expert opinion and --
MR. DAVIS: Well, you have a mechanism to hand control over to the witness.
MR. GOLDBERG: He has the documents there.
MR. DAVIS: You want to hand control to the witness so he can actually page through the

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document himself.
(Discussion off the written record.)
MR. GOLDBERG: Let's go off the record.
THE VIDEOGRAPHER: Off the record at 6:26 p m.
(Break.)
THE VIDEOGRAPHER: We're back on the record at 6:42 p.m.
Q. Mr. Quick, I'm -- I'm looking at Paragraph 108 of your report. You say: The failure to conduct the necessary and comprehensive risk assessment to a critical manufacturing change was in violation of ZHP's own risk man- -- management procedure.
And you cite to this document, Page 11 of 17. What are you -- what are you citing this document for?
A. I'm looking at the document.
(Pause.)
It may have actually been Page 12 or -- let's see. Is it 12? Yeah. The format of risk management includes special systematic and nonspecial, nonsystematic for change control, customer complaint investigation, deviation

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investigation.
It goes on about the type of -- the way it should be formatted.
[redacted]
Q. Other than the EIR and this document that we've marked as Exhibit 22, did you review anything else from the 2010, '11, '12 time frame when this critical change or change control was happening to independently determine whether ZHP followed its own SOPs?
[redacted]

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[redacted]
MR. GOLDBERG: Can you pull up Document No. 20, please?
(Exhibit 24 was marked.)
(Discussion off the written record.)
MR. DAVIS: For the record, the witness has Exhibit 24 on a laptop.
Q. Do you have it up, sir?
A. I do.
Q. Okay. Can you please -- have you seen this document before?
A. I'm not sure whether I have or not.
Q. Well, this document isn't listed in Exhibit A. So can we agree that you haven't reviewed this document before?
A. If it's not in Exhibit A, I probably have not reviewed it.
Q. Okay. This is the change control system SMP. Do you see that?
A. Yes.
Q. Do you see Paragraph 1 of the document refers to the -- explains the purpose?

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A. I do. I see that.

[redacted]

Do you see that?
A. I do.
Q. And if you can scroll down, in the page ending 148, and you'll see the numbers 6, 6.1. This is the procedure page. Correct?
A. Okay.
Q. You -- you --
A. It's taking time to get there because it's got to refresh as I go down the pages.
Okay. I see Page 10.
Q. You've done nothing to independently determine whether ZHP satisfied the SOPs on this Page 6 -- 6 -- on this Page 148. Correct?
MR. DAVIS: Object to form.
You can answer.
A. Well, since I haven't had the chance to

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review it, then I haven't had the chance to evaluate it.
Q. So the answer is, yes, you haven't done anything to independently assess whether ZHP satisfied its internal SMPs?
MR. DAVIS: Objection; asked and answered and to form.
A. I haven't because it wasn't provided to be able to be reviewed. If I had the time to review this, maybe I could come to an opinion on that.
Q. Turn to Paragraph -- you can pull that document down -- Paragraph 111 of your report. Did you -- did you review an org chart for the ZHP Tranon (phonetic) facility?
A. I don't recall having reviewed it.
Q. Well, again, it's not listed in Exhibit A, so you'll agree you didn't review one. Right?
A. Right. If it's not there, I probably didn't.
Q. Well, wait a second. You keep qualifying these answers and we're here at a deposition to be specific, sir, you're an expert witness. Okay. We're going to be specific about this instead of probables and I don't recall.

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MR. DAVIS: Seth.
Q. If it's not in Exhibit A --
MR. GOLDBERG: Hang on.
Q. If it's not in Exhibit A, you didn't review it. Right?
MR. DAVIS: Objection; mischaracterizes the report, mischaracterizes the responses to the notice of deposition.
MR. GOLDBERG: We don't need -- we don't need a speaking objection.
MR. DAVIS: No, I'm not --
Q. If it's not in Exhibit A -- if it's not in Exhibit A, you didn't review it. Right?
MR. DAVIS: Objection; facts not in record, mischaracterizes his responses to the notice, and mischaracterizes his testimony and asked and answered.
Q. I'm going to ask it again, sir. You agree that you didn't review it because if you did it would be in Exhibit A. Right?
MR. DAVIS: Last -- last answer and then you got to move on, Seth.
You can --
A. I -- I didn't review it.
Q. Your Section 111 says: That the head of

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quality assurance -- I -- maybe you can -- what is your -- what is the point of your Paragraph 111?

[redacted]

Q. Did you read -- did you read the entire deposition transcripts for these witnesses?
A. No, I did not read the entire depositions -- depositions.
Q. How did you identify specific excerpts then to rely on?
MR. DAVIS: Objection to form.

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You can answer.
THE WITNESS: Okay.
A. I was provided with particular sections from the law firm that took the depositions.
MR. GOLDBERG: Could you pull up exhibit -- sorry -- Document No. 24 which we'll mark as Exhibit 25, I believe.
THE WITNESS: I'll try to get back there.
(Exhibit 25 was marked.)
Q. Okay. Do you have that --
A. No.
Q. -- testimony in front of you?
A. I do not.
Okay. It's in front of me.
Q. And your criticism in Paragraph 111, is that Ms. Ge, the head of quality assurance was -- wasn't specific enough, wasn't certain enough about whether the technology department provides a risk assessment report. That's your criticism?
A. No, it's not. Sorry.
MR. DAVIS: Objection; mischaracterizes the report and the testimony, both his testimony --
Q. What is --

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MR. DAVIS: -- and Ms. Ge's testimony.
Q. What is your criticism?
A. Okay. Normally, I would've expected the quality function to be handling risk assessments.
[redacted]
Q. Did the FDA note that in its EIR?
MR. DAVIS: Objection -- no to that?
Okay. No objection, you can answer.
A. If we go back to what the FDA said which I had before.
So the FDA noted during the 2018 inspection that ZHP's quality risk management and standard management procedure did not clearly delineate which risk managements and methods and/or tools should be used. And so they had problems with the risk assessment. Regardless of whether FDA did, I -- I agree that there was a problem.
But the real -- the real point here,

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[redacted]
MR. DAVIS: We're getting close to 7 o'clock.
Q. Is it your opinion -- is it your opinion that the technology department should not have a role in the risk assessment?
A. No, I didn't say that and that's not my opinion.
Q. And would it -- is it your opinion that the quality assurance shouldn't have oversight of the risk assessment from a GMP standpoint?
A. Well, I didn't say that either.
[redacted]
MR. DAVIS: Seth, we're at 7 o'clock now, I believe.
MR. GOLDBERG: Okay. Let me just get to the end of this line of questioning. I know somebody needs to leave. So let me just get to the end of this specific questioning.
MR. DAVIS: You've got two minutes to

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wrap it up because our court reporter, we've got to respect the fact that she has another obligation.
(Discussion off the written record.)
MR. GOLDBERG: It's okay. We can go off the record now.
THE VIDEOGRAPHER: Off the record at 7:00 p m.
(Deposition adjourned at 7:00 p m.)

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION § MDL NO 2875 § HONORABLE ROBERT B KUGLER § DISTRICT COURT JUDGE

REPORTER'S CERTIFICATION
DEPOSITION OF JOHN L QUICK
TAKEN JANUARY 27, 2022

I, TAMARA CHAPMAN, Certified Shorthand Reporter in and for the State of Texas, hereby certify to the following:

That the witness, JOHN L QUICK, was duly sworn by the officer and that the transcript of the oral deposition is a true record of the testimony given by the witness;

That the original deposition was delivered to NILDA ISIDRO;

That a copy of this certificate was served on all parties and/or the witness shown herein on

_____

I further certify that pursuant to FRCP No 30(f)(i) that the signature of the deponent:

was requested by the deponent or a party before the completion of the deposition and that the signature is to be returned within 30 days from date

of receipt of the transcript. If returned, the attached Changes and Signature Page contains any changes and the reasons therefor;

was not requested by the deponent or a party before the completion of the deposition.

I further certify that I am neither counsel for, related to, nor employed by any of the parties in the action in which this proceeding was taken, and further that I am not financially or otherwise interested in the outcome of the action.

Certified to by me this 9th day of February, 2022.

Tamara Chapman, CSR, RPR-CRR
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John R. Davis
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February 9, 2022

RE: In Re: Valsartan, Losartan, Et Al
1/27/2022, John Quick (#5025079)

The above-referenced transcript is available for review.

Within the applicable timeframe, the witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason, on the attached Errata Sheet.

The witness should sign the Acknowledgment of Deponent and Errata and return to the deposing attorney. Copies should be sent to all counsel, and to Veritext at erratas-cs@veritext.com

Return completed errata within 30 days from receipt of testimony.

If the witness fails to do so within the time allotted, the transcript may be used as if signed.

Yours,
Veritext Legal Solutions

In Re: Valsartan, Losartan, Et Al
John Quick (#5025079)

ERRATA SHEET

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John Quick Date

In Re: Valsartan, Losartan, Et Al
John Quick (#5025079)

ACKNOWLEDGEMENT OF DEPONENT

I, John Quick, do hereby declare that I have read the foregoing transcript, I have made any corrections, additions, or changes I deemed necessary as noted above to be appended hereto, and that the same is a true, correct and complete transcript of the testimony given by me.

_____ _____

John Quick Date

*If notary is required

SUBSCRIBED AND SWORN TO BEFORE ME THIS _____ DAY OF _____, 20___.

_____

NOTARY PUBLIC

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	§ § § §	MDL NO. 2875 HONORABLE ROBERT B. KUGLER DISTRICT COURT JUDGE

ORAL AND VIDEOTAPED DEPOSITION OF
JOHN QUICK
JANUARY 28, 2022

ORAL AND VIDEOTAPED DEPOSITION OF JOHN QUICK, produced as a witness at the instance of the Defendants and duly sworn, was taken in the above styled and numbered cause on January 28, 2022 from 8:00 a.m. to 12:09 p.m., before JANALYN ELKINS, CSR, in and for the State of Texas, reported by computerized stenotype machine, at the offices of Slack Davis Sanger, LLP, 6001 Bold Ruler Way, Suite 100, Austin, Texas, pursuant to the Federal Rules of Civil Procedure and any provisions stated on the record herein.

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EXHIBITS

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(Witness previously sworn)
VIDEOGRAPHER: Here begins the continuation of the deposition of John Quick. Today's date is January 28, 2022. We are on the record at 8:12 a m.
EXAMINATION
Q. (BY MR. GOLDBERG) Good morning, Mr. Quick.
A. Good morning.
Q. We're going to pick up with the questioning regarding the ZHP portion of your report that we were discussing yesterday. Just before we get started, we sent your -- we sent plaintiff's counsel some documents earlier this morning. Did you look at those documents?
A. I have not seen those documents.
Q. Okay. I want to ask you, in your report from Pages 20 to 25, you've identified five areas that in your opinion ZHP's CGMP's were deficient. Am I correct?
A. I'm not sure of five. Probably -- if you say it's five, it probably is five. I didn't count the number here.
Q. Well, if you just look at the headings there, there are five headings. These are -- these are five general areas.
A. Okay.
Q. So are these the five -- are these five areas -- I guess are these five areas you are claiming

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ZHP's CGMP's were deficient?
A. These are examples of the deficiencies. These are not necessarily all the deficiencies, but these are examples.
Q. Okay. How did you come up with these examples?
A. As I was reviewing documents, I picked examples. I didn't necessarily have any system to pick these particular examples, but they were examples of the CGMB deficiencies that I saw.
Q. Did plaintiff's counsel identify these for you?
A. No.
Q. Did you discuss these five with plaintiff's counsel?
MR. DAVIS: I'm going to -- you can answer the question, but I think we've agreed that communications between the parties and the experts are not subject to disclosure.
THE WITNESS: Well, we've discussed the report. I don't know that we discussed these specific ones.
Q. (BY MR. GOLDBERG) Okay. Can we go through -- I just want to -- I just want to confirm the basis for each of these because you said that they were based on the documents that you reviewed, right?
A. Right.

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Q. Let's look at the first one, the failure to conduct the risk assessment. This was based on -- it looks like Footnote 35, the August 2018 FDA EIR that we looked at yesterday, right?
MR. DAVIS: Objection to form. You can answer.
THE WITNESS: It was also based on my review of what they actually did, the documents.
Q. (BY MR. GOLDBERG) Okay. Which -- which documents again? Because I'm looking at Page 21 of your report. So you're citing to the EIR.
MR. DAVIS: Object to form. Is there a question there?
Q. (BY MR. GOLDBERG) Yes. Which documents other than the EIR are you relying on for this point that ZHP failed to conduct the risk assessment?
A. Well, let's see, which document was that? I don't recall which document it was. It was the document where they had yes/no answers. And it was also, I think, the same document you had yesterday.
Q. Okay. So that -- that's the EIR is one and then the change form, which was Exhibit 23, is what we looked at yesterday, right?
A. Well, I'm not sure which exhibit that was.
Q. Well, that's the one that I showed you

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yesterday that you just referred to. I'm just telling you it's Exhibit 23.
A. Okay.
Q. So if that's the case, those are the two documents that form the basis of this opinion, right?
A. Well, there are -- there were a number of ZHP documents that I looked at. So I'm not sure that those were the only ones.
Q. Well, I'm asking you when you look at this section, Paragraphs 104 through 109 at least on Pages 20 and 21, you're relying on the EIR and that Exhibit 23, right?
MR. DAVIS: Object to form. Also mischaracterizes the report.
You can answer.
Q. (BY MR. GOLDBERG) That was a question.
A. Okay. These are the footnotes I had for those sections. There are a number of other ZHP documents that are in the attachment that I did, in fact, review, and they may include some of those which are not included as footnotes. So I'm not saying that these were the only documents that are in the footnotes. I reviewed the ZHP documents that are in the attachment -- I think it's Attachment A.
Q. Which of the documents on Exhibit A support

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your conclusions in Paragraphs 104 through 109?
A. Well, we'd have to go back and pull each of these documents up and look through them because I'm not sure which ones are which here because we just reference the actual ZHP number.
Q. Okay. So when I look at Exhibit A, the materials related to ZHP, all right, it looks like they sort of follow in order of your opinions. So the first ZHP document you cite at Footnote 35 is the first document here on Exhibit A, 7917. Do you see that?
A. I do.
Q. Okay. And then the next document you cite at Footnote 36, and now we're -- we're tracking along this, Footnote 36 is cited at Paragraph 105. That appears as the second document in Exhibit A. Do you see that?
A. I do see that.
Q. Okay. And then Footnotes 37 through 4 -- through 39, they -- they go back to that EIR, right?
A. Through 30 -- 39, yes.
Q. Yeah. And then 40 and 41, they appear in consecutive order on Exhibit A. Okay? And 40 is what we introduced as Exhibit 23 yesterday. All right? Do you agree with that?
A. I'd have to go back and verify, but it sounds to be accurate.

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Q. Okay. And 41 we introduced as Exhibit 22 yesterday, which was ZHP's SMPs related to the change control. Do you accept that representation?
A. I'd have to go back and check it, but it sounds to be correct.
Q. Okay. Then -- so -- so these are the documents you're citing on -- from 104 to 109. When we look at Exhibit A, the next document after -- after what is 41, which is 950, the next document on Exhibit A ends with 896. Do you see that?
A. I do.
Q. Okay. I'll represent to you that that's an email that relates to the unknown peaks that you discuss later in your report. Okay? Did -- did you rely on that in connection with your opinions from 104 to 109?
MR. DAVIS: Object to form.
THE WITNESS: As I indicated a minute or two ago, I looked at the ZHP documents in totality to rely on my opinions. And so there may have been sections in those -- other documents that I relied upon.
Q. (BY MR. GOLDBERG) What does the email with un -- related to unknown peaks have to do with your opinions with respect to the change control?
MR. DAVIS: Object to form.
THE WITNESS: Well, if we really want to discuss that, we need to pull the document up and take a look at it.

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Q. (BY MR. GOLDBERG) The next document on the list which -- in Exhibit A which ends in 24, is also an email related to -- to unknown peaks. And you cite this later in your report at Footnote 45. Again, I'm just trying to identify the documents that you relied on for this section of your report. And it's okay if you said I -- I relied on the EIR and the change control and I relied on the unknown peak emails for that section of my report. I'm just trying to understand where -- where you're -- where you're drawing your lines.
MR. DAVIS: Object to form and object to the use of the term "documents" as vague. He's relied on other things as well.
You can answer.
THE WITNESS: So I relied on a number of these documents for that opinion.
Q. (BY MR. GOLDBERG) If you relied on the unknown peak related emails for this testimony, why didn't you cite it here?
A. I didn't necessarily put each of the -- a footnote for each of the documents I reviewed for each section. I indicated some of those. And as I've indicated earlier, the points -- the examples in my

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report are just examples. There are other deficiencies that I had seen as I was reviewing the ZHP documents that are not necessarily in my report because these are just examples that applied to the entire class.
Q. The -- let's -- let's go on. So at least you'll agree that for 104 through 108, the only documents you cited as support for those paragraphs are the EIR and the two change process documents we discussed?
A. What I would say is is those are the documents I footnoted.
Q. Okay. And the -- if you go -- if you go on to Paragraphs 110 through 112, and we'll -- this was an area we discussed a little bit yesterday. This is that area where you're talking about the confusion that -- the apparent confusion, as you put it, between these employees about the risk assessment?
MR. DAVIS: Object --
Q. (BY MR. GOLDBERG) And there you're relying on the testimony -- the portions of testimony that you cite here, right?
MR. DAVIS: Object to form. Object to the mischaracterization of his testimony yesterday.
You can answer.
THE WITNESS: Well, that in addition into

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the other documents which -- which were cited in the EIR as well. So just not those.
Q. (BY MR. GOLDBERG) Did you -- and then when we go down to the unknown peaks, then you cite to -- you cite to the four emails in the unknown at Footnote 44 and 45, right?
A. Those are the footnotes I cite in the report, yes.
Q. Okay. In -- on Page 23 when you are talking about this heading ZHP's Failure to Adequately Validate the Valsartan Process Change, for these paragraphs, you're again citing the EIR, right?
A. Those are the -- those footnotes reference the EIR.
Q. Did you look at any testimony related to -- in Paragraph 116, do you recall looking at any testimony in relation to your conclusion that's referenced in Paragraph 116?
A. I may have. I was provided the full depositions for all of the individuals that were deposed from ZHP and Princeton. I did review all of those and there may have been other sections in there as well. Those are exhaustive documents.
Q. I'm sorry. Your testimony today is that you read the full deposition transcripts?

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A. No. That is not what I said. When I said I reviewed, I didn't necessarily review every single paragraph of those depositions. I skimmed through the depositions.
Q. Okay. And yesterday you testified that plaintiff's counsel provided you portions of testimony, right?
A. No.
MR. DAVIS: Object to form. And object to the mischaracterization of his testimony yesterday.
THE WITNESS: No, that is not what I said. I was -- I was provided the full depositions for each of those individuals.
Q. (BY MR. GOLDBERG) Mr. Quick, I just -- yesterday I asked you how did you identify specific excerpts in the testimony. Well, first of all, I said -- I asked you did you read the entire deposition transcripts for these witnesses and you answered, no, I did not read the entire depositions.
MR. DAVIS: Is there a question there?
Q. (BY MR. GOLDBERG) Are you -- are you changing that testimony now?
A. No.
MR. DAVIS: Object to form. Object to the mischaracterization that his testimony is changing

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somehow.
You can answer.
THE WITNESS: No.
Q. (BY MR. GOLDBERG) Are you changing your testimony?
A. No, I am not changing that. I did not read the entire deposition. I skimmed through the deposition. I did not read the entire deposition. We're talking hundreds of pages in some cases. I skimmed through that for pertinent points.
Q. I asked you how did you identify the specific excerpts you relied on and you said I was provided with particular sections from the law firm that took the depositions. Is that -- are you changing your testimony?
MR. DAVIS: Object -- object to form. Object to the mischaracterization that he's changing his testimony.
You can answer.
THE WITNESS: So I asked about specific sections, and I was directed to those sections by the law firm.
Q. (BY MR. GOLDBERG) Did you try to determine whether any of the portions of testimony that plaintiff's counsel provided to you were contradicted by

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other portions of testimony?
MR. DAVIS: Object to form. You can answer.
THE WITNESS: No, I did not do that. As I indicated, I skimmed through the depositions. I didn't necessarily look for that particular situation as you are describing it.
Q. (BY MR. GOLDBERG) If -- if there was testimony that contradicted portions of testimony that were highlighted for you by plaintiff's counsel, would you have wanted to know that in reaching your opinions?
MR. DAVIS: Object to form. Object to the premise of the question.
You can answer.
THE WITNESS: I don't think it was particularly relevant at the time. But if, in fact, those were -- you directed those to me, I could probably review those as potentially an update. But what -- what was stated in depositions I think was pretty clear.
Q. (BY MR. GOLDBERG) What was stated in the portions of testimony that plaintiff's counsel provided to you was pretty clear, and that's your testimony?
MR. DAVIS: Object to form. Object to the characterization that's underlying your question. You can answer.

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THE WITNESS: No, that's not what I said. What I said was I was provided the full depositions. I asked for the relevant portions in the depositions were and the attorneys provided me -- directed me to those particular sections. I had the full entire deposition.

Q. (BY MR. GOLDBERG) Did you ever think -- did you think that plaintiff's attorneys might -- might not provide you the complete picture of the testimony when they are providing you with what they think are the relevant portions?

MR. DAVIS: Object to form.

You can answer.

THE WITNESS: So as I -- as I stated, I was provided the full depositions. I skimmed through the depositions. I was directed to specific areas. No, to answer your question, I did not think that to be the case. And as I also said -- as I have also said if this were to proceed, I would probably do a more in-depth review of the entire deposition. These depositions are very lengthy.

Q. (BY MR. GOLDBERG) Let's pull up Exhibit 20 -- 25.

MR. DAVIS: Is this one of the documents, Seth?

MR. GOLDBERG: This was actually an

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exhibit we -- yes, you should have this. This was the exhibit we -- we ended on yesterday. It was up yesterday.

MR. DAVIS: This is -- oh, okay. All right.

MR. GOLDBERG: This is Exhibit 25. This is the testimony of Jucai Ge.

MR. DAVIS: One second, Seth. Let me hand the document to the witness. Should we -- should we be marking this or --

MR. GOLDBERG: This marked was an -- this was marked as an exhibit yesterday.

MR. DAVIS: Okay. Okay.

MR. GOLDBERG: This was marked as Exhibit 25 yesterday.

MR. DAVIS: So the witness for the record has Jucai Ge's deposition excerpt that was sent to us this morning.

Q. (BY MR. GOLDBERG) And I would like you to turn to Page 276 of the testimony. And I would just like you to read Line 5 and 6.

[redacted]

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[redacted]

Q. Okay. So is it -- is it your opinion when you look at Lines 5 and 6 that Ms. Gi is unclear about who's to provide a risk assessment report?

MR. DAVIS: Object to form and object to the, you know, selective display of, you know, two pages of a deposition transcript.

You can answer.

MR. GOLDBERG: Counsel -- Counsel, that's speaking objection is completely inappropriate. And I'm going to ask you now to just say objection to form. Say vague. Okay. But you don't need to start to make speeches. I'm asking -- I would like the question read back and I would like an answer to the question.

(Requested question was read.)

MR. DAVIS: Same objections.

You can answer.

THE WITNESS: As I indicated in the report, I still believe there was some confusion between those two groups relative to the who was doing the risk assessment, who was responsible for it. Even here she

[redacted]

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[redacted]

and normally, I would have expected the quality function to have a more active role in the risk assessment. So I still stand by the statements in the report.

MR. GOLDBERG: Okay. Can you turn -- can we pull up Tab 20 -- Tab 25 which we'll mark as Exhibit 26?

(Exhibit No. 26 was marked.)

MR. DAVIS: Which one is this?

MR. GOLDBERG: This is the testimony of Min Li.

MR. DAVIS: For the record is -- is Jucai Gi 25?

MR. GOLDBERG: Yes.

MR. DAVIS: Okay.

MR. GOLDBERG: And this, the testimony of Min Li, will be Exhibit 26.

MR. DAVIS: Okay. For the record, I've handed -- I've handed the witness Exhibit 26, which is a two-page document.

THE REPORTER: Hold on. I need to mark it.

Q. (BY MR. GOLDBERG) Now, while we're doing that, if you look at Paragraph 111 of your report, sir, you say that Min Li, the head of the technology department, would testify that it was actually Ms. Ge who would be,

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quote, in a better position to discuss the problem of sodium nitrate quenching resulting in nitrosamines, right? That's what your report says, right?
A. That's what the report says.
Q. Okay. Now when you look at the testimony of Min Li on Page 107, he's asked, (Reading:) Well, whatever you want to call it, he was correct that the sodium nitrate quenching was creating nitrosamines which was a serious GMP problem, correct? And Mr. Li's answer is, (Reading:) In terms of a GMP, you know, Ms. Gi would be in a better position.
So Mr. Li is being pretty clear that Ms. Gi is the person to turn to with respect to the GMP, right?
MR. DAVIS: Object to form.
THE WITNESS: I'm not sure what's different between what you're having me look at than what's in my report.
Q. (BY MR. GOLDBERG) Well, your report takes out of context the phrase in a better position and says nothing about Mr. Li identifying Ms. Gi as the person to talk to with respect to GMP, does it?
MR. DAVIS: Object to form. Object to the characterization of his report.
THE WITNESS: So I still stand by the statements that I believe there was confusion between

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the individuals as to who was responsible and who was conducting the risk assessments.
Q. (BY MR. GOLDBERG) So my -- the answer to my question is, you're correct, my report does not say that Mr. Li directed -- directed -- identified Ms. Gi as the person to talk to with respect to GMP, right?
MR. DAVIS: Same objections.
Q. (BY MR. GOLDBERG) Your report doesn't say that?
A. Well, I'm not sure I understand exactly the point that you're making here.
Q. Well -- okay. I want an answer to my question.
MR. DAVIS: Is -- is -- is there another question?
Q. (BY MR. GOLDBERG) I want an answer to that question. Your report --
MR. DAVIS: He's asked for clarification, Seth.
Q. (BY MR. GOLDBERG) Your report does not say that Ms. -- Mr. Li identified Ms. Gi as the person to talk to with respect to GMP even though that's what his testimony says, correct?
MR. DAVIS: Object to form, object to the characterization.
You can answer.

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THE WITNESS: Again, I'm not sure what you're asking me to agree to.
Q. (BY MR. GOLDBERG) Let's read back the question.
(Requested question was read.)
MR. DAVIS: Restate my objections.
You can answer.
THE WITNESS: Well, if we're looking at this particular section of transcript, that does not say that.
Q. (BY MR. GOLDBERG) It doesn't say in terms of a GMP Ms. Gi would be in a better position?
A. No, it does say that.
Q. But your report doesn't identify that, right?
MR. DAVIS: Object to form.
THE WITNESS: It does say that Ms. Gi would be in a better position to discuss the problem.
Q. (BY MR. GOLDBERG) Your report doesn't say that Mr. Li identified Ms. Gi as the person who would be in a better position in terms of GMP, right?
MR. DAVIS: Object to form.
THE WITNESS: Well, if we're looking at the transcript, the transcript is not stating that. I'm not -- still I'm not sure what point you're trying to make. The point I made in my report was that there was

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confusion between the two groups within the company as to who was responsible and who was conducting the risk assessment. That was the whole point out of that.
Q. (BY MR. GOLDBERG) Okay. Well -- and the point of my question is, it doesn't seem like there's confusion. Mr. Li in his testimony is identifying Ms. Gi as the person who's in a better position with respect to GMP, correct?
MR. DAVIS: Object to counsel's testifying. Object to form.
You can answer.
THE WITNESS: Again, based on the documents I read, I do think that there was confusion between those parties.
Q. (BY MR. GOLDBERG) Answer my question, sir.
MR. DAVIS: He has answered your question, Seth.
THE WITNESS: I just did.
MR. GOLDBERG: Counsel -- Counsel, enough.
MR. DAVIS: Objection, asked and answered.
MR. GOLDBERG: You're interfering -- you're interfering with this testimony at this point. State your objection. That's it.
MR. DAVIS: Objection, asked and answered.
MR. GOLDBERG: I want an answer to my

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question.
Q. (BY MR. GOLDBERG) I would like an answer to my question.
MR. DAVIS: You can answer it one more time. Do you even know what the question is?
THE WITNESS: Do you want to reread the question?
Q. (BY MR. GOLDBERG) Mr. Li identified -- Mr. Li's testimony says that in terms of GMP, Ms. Gi would be in a better position with respect to the risk assessment, right?
MR. DAVIS: Objection, asked and answered. Object to form.
You can answer.
THE WITNESS: Okay. If you're asking if that particular sentence is in this transcript, the answer is, no, it is not.
Q. (BY MR. GOLDBERG) Mr. Li says in terms of GMP Ms. Gi would be in a better position. You agree with that, right?
A. Well, are you asking me to agree with my report?
Q. I'm asking you to agree with what I just asked you, that Mr. Li's testimony says in terms of GMP Ms. Gi would be in a better position.

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A. Yes, and that's what I said in my report.
Q. That's not what you said in your report. That's the problem, sir. Your report leaves out the fact that Mr. Li identified Ms. Gi as being in a better position in terms of GMP.
MR. DAVIS: Object to form.
Q. (BY MR. GOLDBERG) Doesn't it?
MR. DAVIS: Object to counsel's testifying.
You can answer if there's a question there.
THE WITNESS: Yes, I'm not really sure what you're trying to get here because my report indicates that Dr. Li would testify it was actually Ms. Gi would be in a better position to discuss the problem. That's what I said in my report. I'm not sure what's different between what I said in my report and what you just said.
Q. (BY MR. GOLDBERG) Let's go on to Exhibit -- this is Document 28. We'll mark this as Exhibit 27.
MR. DAVIS: Is this --
MR. GOLDBERG: This is the testimony -- John, this is the testimony from Jucai Ge.
MR. DAVIS: I thought this was previously marked, Seth. Is this not previously marked? Oh, is this a different excerpt?
I have a -- I have an April 29th printed out, volume 3. Oh, Jucai Gi. Okay. I know --

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MR. GOLDBERG: No, this is --
THE REPORTER: Jucai Gi.
MR. GOLDBERG: This is -- yeah, that's right. Yeah, it's a mistype -- it's a typo on her name. It's Jucai Gi at least on this thing, volume 2.
MR. DAVIS: Oh, I see. I'm handing the witness -- or I'm handing the court reporter to be marked Exhibit 27.
(Exhibit No. 27 was marked.)
Q. (BY MR. GOLDBERG) Okay. You have that document in front of you, sir?
A. I do.
Q. Okay. At Paragraph 114 of your report, you [redacted]
Do you see that?
A. I do see that.
Q. This is one of the -- and then you cite to her testimony at Section 46. Do you see that, at Footnote 46?
A. I do.
Q. This is one of those portions of testimony that

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counsel highlighted for you?
MR. DAVIS: Object to form.
THE WITNESS: As -- as I said before, I asked what sections that they could direct me to that might be relevant, and this is one of the sections that they directed me to.
Q. (BY MR. GOLDBERG) Okay. Could you read for yourself Pages 169 of this testimony through 170? Just take a minute to do that.
A. Okay.
Q. Okay. When -- when you look at that testimony, [redacted]
MR. DAVIS: Object to form.
THE WITNESS: Well, I have no idea what she was actually thinking when she made these statements. I do not know.
Q. (BY MR. GOLDBERG) That really doesn't answer my question.
[redacted]

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[redacted]

A. Again --

MR. DAVIS: Object to form.

THE WITNESS: Again, as I indicated, I have no idea what she was thinking. I just considered this to be an appropriate analogy.

Q. (BY MR. GOLDBERG) Okay. So you -- you -- you acknowledge it's an analogy, right?

A. She obviously was trying to make an analogy.

Q. Okay. It might not be a good analogy, right?

A. I'm sorry. I missed that.

Q. It might not have been a good analogy, right?

A. It might not have been a good analogy, correct.

[redacted]

MR. DAVIS: Object to form.

THE WITNESS: So you're asking me to try to

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understand what she was thinking when she made this and I don't know.

Q. (BY MR. GOLDBERG) Okay. So you don't know, but yet in your report you want to -- you reach some conclusion about what she's saying, right?

MR. DAVIS: Object to form.

THE WITNESS: Well, that's -- that's not what I said in 114.

Q. (BY MR. GOLDBERG) Do you feel like in -- in 114, did you fairly characterize Mrs. Gi's testimony on 169 and 170?

A. I believe I did.

[redacted]

MR. DAVIS: Object to form. Objection, asked and answered.

You can answer again.

THE WITNESS: Again, I'll say as I said before, I have no idea what she was trying to accomplish when she made this statement in the deposition.

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Q. (BY MR. GOLDBERG) Okay. Let's turn to Page 1 -- I'm sorry, Page 23 of your report and I'm looking at Paragraph 116. You can pull down that testimony if you'd like. Paragraph 116.

A. Okay.

Q. You say, (Reading:) The real reason for making this critical change was not so much in reducing isomer conversion and increasing yield as had been stated, but rather to save money.

And then you go on to quote the EIR which quotes -- the EIR quote -- says -- I'm sorry. Let me -- let me ask that question differently.

You quote the EIR which quotes a statement by Jun Du, the executive vice president of ZHP, correct?

A. That is correct.

Q. Okay. Did you look at Mr. Du's testimony about what he said with respect to this statement?

A. I may have. But I was -- what I'm referencing here is what he told the FDA investigator.

Q. Mr. Du's testimony is not listed as any of the materials you reviewed. So you didn't review his testimony?

A. Right. If it's not listed here, then I did not review it.

Q. Did you review any -- do -- do you recall

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reviewing anybody's testimony as to this particular -- this particular portion of the EIR that you're reporting from?

A. Well, there are a number -- there are a number of transcripts that I was provided that I did -- as I indicated, I did review. I've not -- I have no idea whether I reviewed all of them -- exactly what I reviewed at this point. But the situation here relative to the statement was basically he was telling the FDA investigator that the real intent for making this change was to save money. That was the point of that Section 116.

Q. Can we pull up document No. 31 in our list, which we'll mark as Exhibit 28?

(Exhibit No. 28 was marked.)

MR. DAVIS: For the record I'm handing the witness the May 28th Jun Du face page and one page of deposition testimony.

Q. (BY MR. GOLDBERG) If you look, sir, Page 232 of that testimony --

MR. DAVIS: Seth, the court reporter has just marked it and handed it to the witness.

Do you want to take a moment to review?

THE WITNESS: Sure. Okay. I'm looking at 232.

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Q. (BY MR. GOLDBERG) In 232 Mr. Du says, (Reading:) I did not state that the cost reduction would cause dominant well market share.

Do you see that?

A. I do see that.

Q. Okay. This answer on Page 232 -- let me go back.

At 231 plaintiff's counsel was reading to Mr. Du the exact language that you quote at Page 116 of your report. Do you see that?

A. I do see that.

Q. Okay. And Mr. Du says, (Reading:) I do not agree with that -- this statement here. I did not make such an apology, and I do not understand why it was written here. I did not state that the cost reduction would cause dominant world market share.

Do you see that?

A. I do see that.

Q. Is this the first time you've seen that Mr. Du denies making this statement that -- that you've put in Section 116?

A. This is the first time I've seen that statement, yes.

MR. GOLDBERG: Okay. Can we pull up document No. 32, please? And we'll mark this as

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Exhibit 29.

(Exhibit No. 29 was marked.)

MR. DAVIS: For the record, I'm handing the court reporter to be marked the May 5th deposition face page of Linda Lin and a couple of -- two pages of deposition testimony.

Q. (BY MR. GOLDBERG) If you could look, sir, at Pages 207, 208, 209, 210, I'll direct you to specific portions, but...

MR. DAVIS: Do you want a few moments to review since he's asking you to look at multiple pages?

THE WITNESS: Yes.

MR. DAVIS: Okay.

Q. (BY MR. GOLDBERG) And I'm going to ask you about 207, 208, 209, 210.

MR. DAVIS: Okay. The witness is going to read those pages.

THE WITNESS: Okay.

Q. (BY MR. GOLDBERG) Okay. On Page 208 -- well, let's go down to 209. You see on 209, Ms. -- Ms. Lin -- do you know who Linda Lin is? Do you know what her role was at ZHP?

A. There are a number of individuals. I'd have to go back and determine what specific role she had. There are a number of individuals, so...

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Q. Ms. Lin was the -- the head of regulatory at ZHP. She was asked on Page 209, she was read that same portion of the EIR that you cite in 116. Do you see that?

A. I do see that.

Q. And she says, (Reading:) In my recollection I do not recall Mr. Du saying this to the FDA. This is not what I can recall. And second, based on my [redacted]

Do you see that?

A. I do see that.

Q. Is this the first time you've seen testimony from Ms. Lin that refutes the notion that Mr. Du said what -- what you've quoted in Section 116 of your report?

A. This is the first time I've read what -- what you've just provided to me.

Q. Okay. I just want to ask you a few more questions about your report.

Pages -- let's -- let's go to Section 4 in your report, these -- these Paragraphs 117 through 126. You rely on a 2010 email from Remonda Gergis, and this

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is at Paragraph 118 in the section entitled, "ZHP's Failure to Adequately Train Quality Assurance." Am I correct about that?

MR. DAVIS: Object to form.

THE WITNESS: Well -- well, 118 refers to [redacted] where I see that in Section 118.

Q. (BY MR. GOLDBERG) That's the -- that's the words that you used.

A. I'm just --

Q. The heading -- heading No. 4 says --

A. Oh, okay. Okay. At the top, yes. But I thought we were referring to Section 118.

Q. Well, I'm -- I'm looking at this section of your report. But you're relying on this 2010 email when you're talking about ZHP's -- in your view ZHP's failure to adequately train quality assurance personnel, right?

MR. DAVIS: Object to form. Mischaracterizes the report.

You can answer.

THE WITNESS: So I am relying upon what

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Ms. Gergis, if I'm pronouncing her name correctly, stated in that email, yes.
Q. (BY MR. GOLDBERG) And you're relying on it for what purpose?
A. Well, to show that ZH -- ZHP was an operation out of control.
Q. And her email is in 2010, right?
A. Yes.
Q. Is it your opinion that her email related to ZHP's operations between 2010 and 2018?
A. I'm relying on what she said relative to what she saw in 2010.
Q. Okay. So your opinion is about ZHP in 2010, right?
MR. DAVIS: Object to form. Object to the mischaracterization.
THE WITNESS: I'm relying on the fact of what she found when she was there in 2010. I believe there's other statements. But I think she came back a year or two later and had similar situations.
Q. (BY MR. GOLDBERG) Did you -- if you look at Paragraph 119, you cite another inspection by Ms. Gergis in 2014, right?
A. I do.
Q. Okay. And what do you rely on that inspection

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for?
MR. DAVIS: Object to form.
THE WITNESS: Well, I'm relying on the fact that she came back in 2014 to do another inspection and she observed similar CGMP issues.
Q. (BY MR. GOLDBERG) Did you identify any instance between 2010 and 2014, the dates of these documents, where the FDA found CGMP issues at ZHP?
A. You know, as I've said a number of times, this report only has examples of the CGMP examples that I found. It's not all exhaustive. So the answer is I have not looked at every possible document. I looked at specific examples relative to CGMP deficiencies that applied to the class.
Q. So the answer to my question is no?
MR. DAVIS: Object to the mischaracterization.
THE WITNESS: I did not reference any -- any inspections in the period of time that you're talking about in my report.
Q. (BY MR. GOLDBERG) Were you aware that the -- that the FDA did not find any objectionable CGMP conditions at ZHP between 2010 and 2015?
A. I did not review those documents relative to this report.

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MR. GOLDBERG: Okay. I -- I'm going to conclude my examination now.
THE WITNESS: Take a break?
MR. DAVIS: Do you want to take a break?
THE WITNESS: Can we take a break?
MR. DAVIS: Yeah. The witness has indicated he wants to take a five-minute break. We've been going for about an hour any ways.
VIDEOGRAPHER: Off the record 9:09 a m.
(Brief recess.)
VIDEOGRAPHER: We are back on the record at 9:18 a m.
EXAMINATION
Q. (BY MR. STOY) Morning, Mr. Quick.
A. Good morning.
Q. My name is Frank Stoy, and I represent the Mylan defendants in this litigation. I'm going to ask you some questions this morning about the portion of your report and your opinions that pertain to Mylan. Do you understand that?
A. Yes.
Q. Okay. Now I want to direct your attention first to Page 36 of your report and specifically to Paragraph 191. Let me know when you're there.
A. I am.

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Q. Okay. I see in the back part of that paragraph where you say, (Reading:) The corporate quality assurance deficiencies described herein are the type of quality assurance activities that would have impacted each of the manufacturer defendants valsartan products equally and in the same manner.
Did I read that correctly?
A. You did.
Q. Okay. I want to ask you about this statement as it pertains to my client. Okay?
So earlier in your deposition, I -- I heard you testify about a 2011 process change by ZHP; is that correct?
A. That's correct.
Q. And -- and is it your understanding or your belief that that process change lead to the presence of the nitrosamine impurity in ZHP's API?
A. It would appear to be the case. My comment [redacted]
Q. Are you aware that ZHP used a different process to manufacture valsartan API than my client, Mylan?
A. I'd have to go back and review those documents.

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Q. So is your testimony that you're not sure as you sit here today whether Mylan and ZHP used the same process to manufacture valsartan API?
A. Again, I reviewed a lot of documents. We could go look at those documents if we wanted to. I'm just not certain at this point today this morning.
Q. Have you reviewed documents that reflect the different processes used by the different manufacturers?
A. As I said before on this report, this report only attempted to identify specific -- certain examples to demonstrate the overall CGMP deficiencies that are pertained to the class, and I have not reviewed everything.
Q. So as you sit here today, you don't know whether any of your observations regarding ZHP's manufacturing process would apply to Mylan or not, correct?
MR. DAVIS: Objection. Outside of the scope. Asked and answered and he's not a process chemist.
But you can try.
THE WITNESS: So as I've said, I've reviewed the various documents and I put the CGMP deficiencies as I've seen them. You're asking a very specific question which I may or may not have seen, so

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the answer is I don't know because I may not have looked at that because this was not an exhaustive report. It was only to identify examples.
Q. (BY MR. STOY) Right. You weren't looking at the different manufacturer's process chemistry; you were just looking at GMP issues, correct?
A. Well, process changes do impact CGMP. I was -- but I was looking at the CGMP aspects.
Q. Are you aware of how the nitrosamine impurity that was detected in Mylan's valsartan API was formed?
A. I may be, but that's not an area that I looked at relative to my report.
Q. Did you ever review Mylan's root cause analysis related to the nitrosamine impurity?
A. Well, I did review, as I indicate in my report, the risk assessment that was conducted by Mylan.
Q. The risk assessment that you reference in your report, I believe, was a 2014 document; is that correct?
A. I have to go back and make sure that's a correct date. I'm not sure. If you say it's that date, it probably is. But I'm not certain what the date was without looking at the document.
Q. So if it was a -- assuming I'm correct that it's a 2014 document, that document would not be Mylan's root cause assessment with regard to the nitrosamine

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impurity that was detected in 2018, correct?
A. Well, I don't know, so I can't say correct because I don't know. I'd have to go back and look at the documents. Again, as I said I did not do an exhaustive search of documents. My focus here was to look at the specific examples of CGMP deficiencies that apply to the class.
Q. Is it fair to say, sir, that if the root cause assessment that Mylan conducted in 2018 is not listed on Exhibit A to your report, then you didn't review it in preparing your report, correct?
A. Well --
MR. DAVIS: Object to form.
You can answer.
THE WITNESS: So the documents that I reviewed, again as I said, I didn't necessarily review all documents. I only reviewed examples that I -- as I said in my report, they were examples. It was not an exhaustive report. It was not intended to be an exhaustive report. If there were further work beyond this on merits report, probably would get into that type of thing.
Q. Sure. I understand that's your testimony. But I also heard you testify yesterday that if it's not in Exhibit A, I probably haven't reviewed it. Do you

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remember testifying to that?
MR. DAVIS: Object to form. Object to the mischaracterizing his testimony.
You can answer.
THE WITNESS: Well, the documents that I've included in my report are the documents that I reviewed that are shown in Exhibit A.
Q. (BY MR. STOY) Right. And I don't see the 2018 root cause analysis that Mylan conducted in Exhibit A. So if it's not in there, that means you probably didn't review it, right?
A. If it's not in there, I did not review it for the purposes of this report.
Q. Have you ever reviewed the results of Mylan's internal testing for nitrosamine impurities in valsartan API?
A. I -- I may have. But that was not the purpose of this report. The purpose of this report was to identify examples of CGMP deficiencies.
Q. (BY MR. STOY) Have you ever reviewed FDA's published testing results for nitrosamine impurities in Mylan's valsartan's finished dose?
A. I may have seen those documents, but that was not particularly relevant to this particular report relative to CGMP deficiencies.

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Q. Okay. So you may have seen those, you may not have, but you didn't consider those documents in preparing this report, correct?
A. That is correct.
Q. Have you ever reviewed Mylan's valsartan recall notices?
A. I may have seen those, but that was not pertinent to this report.
Q. Okay. So again, you wouldn't have considered those in preparing this report, right?
A. That's correct because I was focusing on examples of CGMP deficiencies that applied to the class.
Q. Generally speaking, do you understand that Mylan recalled valsartan containing medications in November and December of 2018?
A. I don't specifically remember that. But I know there are number of recalls by number of manufacturers in that timeframe.
Q. Are you aware, sir, that none of Mylan's valsartan API contained NDMA above the FDA's allowable intake limits?
MR. DAVIS: Object to form.
THE WITNESS: That's not something I reviewed. What I reviewed were the CGMP deficiencies. And I think as I said yesterday, the CGMP deficiencies

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would apply to all the products and wouldn't necessarily matter whether they contained the contaminants or not. The fact that the CGMP deficiencies would indicate that all products were adulterated as I said yesterday. But, no, that wasn't relevant to this particular report.
Q. (BY MR. STOY) Were you aware that the FDA had set allowable intake limits for NDMA and NDEA?
A. There -- there are a number of documents that the FDA has published relative to the allowable limits, et cetera. But again, that was not relative to my particular report.
Q. Sure. I'm not asking whether it was relevant to your report. I'm asking whether you were aware of it; yes or no?
A. I'm aware there were very certain limits set at various times, but again, those are not documents that I reviewed as part of my report.
Q. So you wouldn't know one way or the other whether Mylan issued a recall for any medications related to NDMA, correct?
MR. DAVIS: Object to form. Did you say NDMA or NDEA, Frank?
MR. STOY: NDMA.
MR. DAVIS: Okay. Thank you. Object to form.

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THE WITNESS: So again, I may have seen those, but that wasn't a subject of my report. So I did not review those documents relative to my report.
Again, I want to state again that my report only list examples. It was not an exhaustive search of everything. It was examples related to the CGMP deficiencies related to class.
Q. Do you have an understanding as to whether all of Mylan's valsartan API contained levels of NDEA that was above FDA's allowable intake limits or is that not something you consider?
A. Well, I didn't -- that -- that wasn't relative to my report. The -- the one document I would probably [redacted] 2012, 2013. So I'm aware of that. I'm not quite sure how that relates to anything because that's not necessarily relevant here.
Q. Sure. And that document you just mentioned, that's a ZHP document, right?
A. That was a ZHP document, right.
Q. So that wouldn't have anything to do with

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Mylan, right?
A. Again, I didn't try to make the inference in my report that it did.
Q. I'm sorry. I didn't -- I didn't hear your answer.
A. I said I did not try to make that inference in my report.
Q. Right. Because ZHP and Mylan are different API manufacturers, correct?
A. Right.
Q. They have different supply chains, right?
A. That's correct.
Q. Would it affect your opinions one way or the other if you learned that some of the batches of Mylan's valsartan API contained NDEA levels below FDA's allowable intake limits?
MR. DAVIS: Object to form. Object to the extent it assumes facts not in evidence.
You can answer.
THE WITNESS: No, I would not because that was not the purpose of my report. The purpose of my report was to identify the GMP deficiencies that I observed.
Q. (BY MR. STOY) And because you're not -- you can't recall ever reviewing Mylan's NDEA testing, you're

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not aware one way or the other if there was a 20-fold difference between the lowest detected level of NDEA and the highest detected level of NDEA; is that right?

MR. DAVIS: Object to form.

THE WITNESS: Again, that's not -- not a situation that I reviewed because it was not relevant to identifying the CGMP deficiencies.

Q. (BY MR. STOY) So you don't think it's relevant whether there was variance from one batch to the next regarding the content of NDEA in Mylan's API. Is that your testimony?

MR. DAVIS: Object to form. Object to the extent it mischaracterizes his testimony.

THE WITNESS: That's -- that's not what I said. If there were varying levels, it would certainly indicate that there was something out of control which you would want a consistent process. But that's not something I reviewed relative to this report.

Q. (BY MR. STOY) Why is it that you don't think that it's relevant whether the levels were different from one batch to the next for the purposes of your report?

A. Because I was identifying CGMP deficiencies. And as I said before, relative to the CGMP deficiencies, it's not relevant whether there was any contaminant at

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all if they were not made in a compliant manner.

Q. I want to talk a little bit about what you did to form the basis for your opinions regarding Mylan.

Based on your report, it looks to me like you went through certain documents and deposition testimony that was provided to you by plaintiff's counsel; is that correct?

MR. DAVIS: Object to form. Object to the characterization.

You can answer.

THE WITNESS: Yes, these documents were provided by plaintiff's counsel. As I said yesterday, initially, when I started this process at the very beginning, I had a list of documents that I thought would be useful to review as part of this overall process. This goes back some time ago. So it may have been the documents I had requested. It may have been other documents. So I'm not sure which -- which would fall into which category. But the documents I reviewed for the report are the ones that are listed in Exhibit A.

Q. (BY MR. STOY) Right. And you -- I think you testified earlier that with respect to the deposition testimony you didn't review those documents in their entirety; is that correct?

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A. That's not what I said. What I said was I was provided with a complete transcripts and I skimmed through the transcripts. I did not necessarily read every sentence in the very extensive depositions provided. I skimmed through and I asked for what -- where there might be specific references for the things I was looking for. But if you -- I want to make sure you understand that I didn't necessarily review every sentence in the deposition. I wanted to review the pertinent points relative to my report.

Q. How did you -- and I'm just asking with respect to the Mylan deposition transcripts, how did you determine which portions of those transcripts would contain pertinent information?

A. So it's the same as I said before is I asked counsel what sections might relate to the particular aspects that I'm trying to review here, and they directed me to those sections.

Q. And those were the sections or some of the sections that ultimately appear in your report?

A. That's correct.

Q. In the text, correct?

A. That's correct.

Q. And with respect to -- so putting deposition transcripts to one side, with respect to the documents

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that you referenced, how did you go about selecting those documents for inclusion in your report?

A. So as I've indicated, I tried to pull up examples that would relate to -- CGMP deficiencies that related to the class, and again, I didn't necessarily review other -- I may have reviewed other documents that would also be relevant, but I only included examples in my report.

Q. Did you read the full documents that are included in your report?

A. Well, some of these documents are hundreds of pages. So I reviewed the -- I reviewed the sections that were relevant to the sections I referenced.

Q. And how did you -- same question as with the deposition testimony, how did you go about determining which sections were relevant?

A. Well, for example, let's go to my -- my Paragraph 130. In that regard I reviewed the entire document. This had to do with the risk assessment that was eventually ultimately classified as low risk. I did review that entire document because the entire document was relevant to my report.

Q. Look specifically at Paragraph 131 in your report.

A. Which paragraph?

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Q. Well, actually, first of all, I want to ask you about Paragraphs 129 through 133 in your report --
A. Okay.
Q. Let me know when you're there.
A. I'm there.
Q. Okay. You made some statements here about Mylan's internal operations, correct?
A. When you say, "internal operations," I make reference to the risk assessment in 2014.
Q. Right. That would be an internal Mylan document, correct?
A. That's correct.
Q. These observations that you make in 129 through 133 would not be pertinent to any other defendant besides Mylan, correct?
A. That's probably the case because these were Mylan risk assessments.
Q. Sure.
MR. DAVIS: Let me -- I'm going to place an objection on that last question.
THE WITNESS: So I guess maybe to clarify that it would be relevant to Mylan and the class related to Mylan products.
Q. (BY MR. STOY) What do you mean by that?
A. Well, it -- it would relate to all the products

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and pills that were distributed by Mylan relative to the specific issue.
Q. Look specifically at Paragraph 131 on Page 26 there. Take a second and read it for me. Not out loud. Just to yourself.
A. Okay. I've read it.
Q. Okay. You make reference to some chromatography testing of the solvent ortho-xylene; is that correct?
A. I do.
Q. Did you personally review any of that chromatography testing?
A. I did not review the specific chromatograms. I did not review those. It wasn't relevant to my report to review the specific chromatograms.
Q. So you did not undertake any analysis of yourself of these so-called unknown peaks; is that correct?
A. No, I relied on -- on the Mylan testimony to indicate that they never investigated these unknown peaks. That -- that was what I looked at. Mylan themselves indicated they had not done a -- investigated the unknown peaks.
Q. So you're not offering any opinion of whether Mylan should or should not have investigated these

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peaks, correct?
A. My comment -- I'm sorry.
MR. DAVIS: Object to form. Go ahead.
THE WITNESS: So my comment is they should have investigated these peaks and -- which is what the FDA also got into as well. And so not properly investigating these unknown peaks was the -- was the issue. But I'm not offering an opinion on the specific chromatograms.
Q. (BY MR. STOY) Right. You're just restating what you think FDA said with regard to this --
A. No.
Q. -- because you didn't analyze them yourself, right?
MR. DAVIS: Object to form. Objection to the mischaracterization of his testimony.
THE WITNESS: No. What you said is not correct. I also reviewed the depositions from the Mylan employees relative to the situation.
Q. (BY MR. STOY) In Paragraph 132, which you just referenced, you state that FDA made some observations about unknown peaks in some document; is that right?
A. I do.
Q. Do you know if the unknown peaks that you reference --

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THE REPORTER: Wait. I can't hear you.
THE WITNESS: I can't either.
MR. DAVIS: Sorry, Frank. We didn't get that. Can you repeat the question?
MR. STOY: Sure. Can -- can you hear me now?
MR. DAVIS: Yes.
Q. (BY MR. STOY) Do -- do you know if the unknown peaks that you reference in Paragraph 132 are the same ones referenced in Paragraph 131?
A. I'm not certain, but it's not particularly relevant. The real key is that Mylan should have been investigating these unknown peaks. So whether the same or not is not relevant. The fact is that they weren't properly investigated. That's the point I was making.
Q. Well, if they're not the same, how do you know that they weren't properly investigated?
MR. DAVIS: Objection to form. Objection to the mischaracterization of the testimony.
You can answer.
THE WITNESS: Mylan themselves in their depositions basically stated that.
Q. (BY MR. STOY) How do you know that the deposition testimony is referring to the same peaks?
A. I don't. But it's not relevant. It doesn't

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matter.
Q. So your testimony is that any failure to investigate any unknown peak anywhere in the company somehow relates to valsartan?
MR. DAVIS: Objection.
Q. (BY MR. STOY) I'm not following your testimony, sir.
MR. DAVIS: Object to form. Objection to the mischaracterization of his testimony.
THE WITNESS: So what I said and I'll say again is if in a chromatogram you have unknown peaks, it's the responsibility of the company to investigate and determine what those unknown peaks represent.
Q. (BY MR. STOY) And you don't know whether they were investigated or not beyond what you read in documents, right?
A. Well, I'm referring back to what Mylan themselves said.
Q. Take a look on the next page. You cite to an FDA inspection document there, right? I think it's -- it's in Footnote 68, 69, and 70, it's the same document; is that right?
A. That's right.
Q. You quote some excerpts from that document, correct?

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A. I do.
Q. Take a look at Paragraph 136 on Page 27. Let me know when you've had a chance to read it.
A. Okay.
Q. You're quoting the February 28, 2020 Unit 7 FDA establishment inspection report in that paragraph, correct?
A. I am.
Q. Tell me what analysis you performed related to this document.
MR. DAVIS: Object to the form. Vague.
You can answer.
THE WITNESS: I'm referencing what the FDA found during the inspection of which they included in their established inspection report.
Q. (BY MR. STOY) Right. You're just quoting what FDA says, right?
A. I am quoting what FDA says, because I was not in the facility, but the FDA was and they -- they issued their report.
Q. So you weren't able to do any independent analysis to verify what FDA said, correct? You're just repeating what they put in the report?
A. And I have no reason to believe that the FDA was incorrect.

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Q. Did you do anything else to render these opinions that appear on this page as they pertain to Mylan besides review this report?
MR. DAVIS: Object to form.
THE WITNESS: Well, I reviewed the documents I've listed in my Exhibit A, which may include other things. And again, as I said before, these were just examples.
Q. (BY MR. STOY) Are you aware of which Mylan facilities manufacture valsartan API?
A. I may be. I just don't recall at hand.
Q. Would you agree with me that FDA observations at a facility that did not manufacture valsartan API would not be relevant to your report?
MR. DAVIS: Object to form.
THE WITNESS: So my report addressed the -- addressed the points relative to CGMP deficiencies. That's what was relevant, the CGMP deficiencies that were observed.
MR. DAVIS: Would you read my question back, please, Madam Reporter?
(Requested question was read.)
THE WITNESS: They would be --
Q. (BY MR. STOY) I would like you to answer that question.

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A. They would be relevant because of the indicative of a corporate noncompliance. So if it occurs to one facility, it would probably occur at another facility from a CGMP standpoint, and Mylan should be responsible ensuring that all facilities are CGMP compliant.
Q. So it's your testimony that CGMP issues that occur at one facility in a company -- in a global company are also likely to occur at another facility in a global company?
MR. DAVIS: Object to form. Objection to the mischaracterization of his testimony.
THE WITNESS: That's not what I said. What I said was if a CGMP deficiency occurs -- occurs in one operation, most pharmaceutical companies would go and investigate the other facilities to ensure they don't have similar situation in those to facilities because they could well have those situations.
Q. (BY MR. STOY) So my hand has facilities in, let's say, Puerto Rico. If the FDA goes into Puerto Rico and makes observations about GMPs, it's your -- it's your position that Mylan then should initiate investigations at all of its other facilities all over the world?
MR. DAVIS: Object to form. Objection,

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incomplete hypothetical.
You can answer.
THE WITNESS: So if deficiencies are found as for your example in a Puerto Rican facility, I think Mylan should, in fact, go and investigate the similar CGMP deficiencies occurring at other facilities. And I believe that's the expectation of the agency, and I would expect that to occur. And just going back to my prior life at Baxter, that's what we did.
Q. (BY MR. STOY) So if you had FDA make observations that were specific to one facility when you were at Baxter, your testimony is that Baxter would initiate investigations at all of its other manufacturing facilities?
A. What I said -- what I said was if we had a situation in one facility, we would -- had GMP deficiencies, we would ensure that we examine the other appropriate facilities to ensure we didn't have similar deficiencies and/or put corrective actions in place not have those situations.
Q. The report that -- let's go back to the Unit 7 EIR, which it comes from a 2020 inspection. You'd agree with me that -- that the 2020 inspection occurred years after the valsartan recall, correct?
A. It did occur after the recalls, yes.

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Q. And are you aware of the fact that at the time of that inspection, Mylan's valsartan was back on the market?
MR. DAVIS: Object to form and objection to the mischaracterization of the facts.
THE WITNESS: So to answer your question, I may be aware of it. That's not relevant to my report.
Q. (BY MR. STOY) Why is it not relevant to your report?
A. Because in my report I used examples for CGMP deficiencies that existed within Mylan, and whether they were back on the marketplace at some point in the future is not relevant to my report as to what happened at the time I indicated there were CGMP deficiencies. All that says is they eventually corrected them.
Q. Okay. But you're citing from a 2020 report and a 2020 inspection that occurred after FDA had allowed Mylan to return valsartan to the market, right?
MR. DAVIS: Object to form. Again, objection to the mischaracterization of the facts.
THE WITNESS: I don't know the timing on when valsartan came back to the -- Mylan's product came back to market. Again, it's not relevant. The fact that it came back is totally irrelevant to my report relative to the CGMP deficiencies.

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Q. (BY MR. STOY) You don't know one way or the other whether Unit 7 ever manufactured valsartan, right?
A. Again, no. And my -- but my point is -- and we went through extensively yesterday in this deposition -- it doesn't matter if there is CGMP's deficiencies in a facility. All of the -- all of the drug products produced in that facility could be considered to be adulterated. So if there's an issue in one part of the facility, it would apply to other parts of the facility.
Q. Sure. But if that facility didn't make valsartan, then it wouldn't apply to valsartan, right?
MR. DAVIS: Objection.
You can answer.
THE WITNESS: So again, my -- my -- my comments related to CGMP deficiencies not necessarily related to valsartan related to CGMP deficiencies, but it does apply to the class. And the point was if there was a deficiency -- hold on a second.
MR. DAVIS: Sorry. The witness lost his microphone.
THE WITNESS: If there was a deficiency in one part of the facility, there might be deficiencies in another part of the facility.
Q. (BY MR. STOY) Okay. But that still doesn't explain to me how that would apply to valsartan which if

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it was not manufactured at that facility.
MR. DAVIS: Object to form.
THE WITNESS: So I'm saying the same thing again is that if there's a CGMP deficiency in one operation in one part of the facility or another facility, it should be the responsibility of the pharmaceutical manufacturer to ensure that those deficiencies are corrected across the operations, all the operations.
But that's not -- that's not really the subject of my report. I didn't get into that kind of detail. My point is my report identified examples of CGMP deficiencies. There may be others and if I had additional information at some point, we would review that information in light of this. This is not a merits report. It's -- it's an attempt to identify examples of CGMP deficiencies.
Q. (BY MR. STOY) Sure. But just to be clear, the document that you are relying on on this page of your report in order to form your opinions is this Unit 7 EIR document, right?
MR. DAVIS: Object to form.
Q. (BY MR. STOY) That's the one you're quoting, right?
A. That's -- that is the one I'm referencing. If

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you're referring to Section 136, that's the one I'm referencing, yes.

Q. And you don't believe that the timing of when FDA issued any warning letter to Mylan related to a facility that manufactured valsartan, you don't believe the timing of that is relevant to your report. Is that your testimony?

MR. DAVIS: Objection to form and object, vague and ambiguous.

You can answer.

THE WITNESS: The timing was not the aspect of my report. The issue was identified what I considered to be seriously GMP deficiencies that existed and I reference those. But the timing relative to any document that the FDA would have put out was not particularly relevant to my examples that I reference in my report.

Q. (BY MR. STOY) Could Mylan have returned to the market with valsartan without FDA's approval to do so?

MR. DAVIS: Object to vague and ambiguous as to Mylan's return to the market of valsartan.

You can answer.

THE WITNESS: I don't know. They may or may not have been able to. I don't know because that wasn't a topic that I reviewed as part of my report.

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Q. (BY MR. STOY) Well, I'm not -- I'm asking you a more general question based on your, you know, 40-plus years of experience in this industry.

When a -- when a company takes a product off the market, can that company put the product back on the market without FDA's approval?

MR. DAVIS: Object to form. Objection, improper hypothetical. It's contrary to the facts of the case.

THE WITNESS: So every example would be different. So I -- you're giving me a hypothetical situation. In some cases the FDA might want to approve the product going back to the market. Other cases they may not have to. It really depends. And again, it's not relevant to what I was looking at and that was not a topic, a focus I was looking at relative to my report relative to the CGMP deficiencies.

Q. (BY MR. STOY) So you don't -- you don't know whether Mylan ever went back on the market with valsartan or not; is that your testimony?

MR. DAVIS: Object to -- sorry, Frank, I didn't mean to cut you off there. Do you want to repeat that?

Q. (BY MR. STOY) Sorry.

You do not know one way or the other

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whether Mylan ever went back on the market with valsartan?

A. So I -- I may have seen that they went back to the market. I don't know. But again, I'll say again it wasn't relevant to the CGMP deficiencies that I was reviewing and putting to my report.

Q. The FDA never placed Mylan on import letter, correct?

A. I don't believe so, but I'm not certain. And again, that's not relevant to my report.

Q. Are you aware that the facilities that manufactured valsartan API continued to supply drug products with FDA approval throughout the entire time period that we've been discussing?

A. I'm not particularly aware of that. But again, it's not relevant. All I'm going to say again what I identified were examples of CGMP deficiencies. The statement that you make is not relevant to my report and it's not relevant to what I reviewed.

Q. Do you think the FDA would allow a drug manufacturer to sell adulterated and misbranded products in the United States?

MR. DAVIS: Object to form.

THE WITNESS: Well, it would depend upon that particular situation and what the FDA determined.

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I'm not going to speak for the FDA, what the FDA may or -- might or might not do.

Q. (BY MR. STOY) So you don't have an opinion on that one way or the other?

A. I don't because it's not relevant, and I'm not going to speak for the FDA. FDA does different things relative to different circumstances. And I'm not going to speak for the FDA.

Q. You testified yesterday that when you were at Baxter, the FDA issued a warning letter to the company in, I think, 2000; is that right?

A. I did -- so I can't -- you're a little --

Q. Oh, I'm sorry. I'm sorry. I apologize.

You -- you testified yesterday that when you were with Baxter, the FDA issued a warning letter to one of Baxter's facilities; is that right?

A. I was provided with a warning letter yesterday that showed -- it showed that Baxter did receive a warning letter, yes. I --

Q. Right. I think you were copied on that document, right?

A. I was.

Q. And I believe you testified, and if I misstate this, correct me, but I believe you testified that based on that warning letter, you considered all the products

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manufactured at that facility to be adulterated as a result of the warning letter. Is that your testimony?
A. So that -- I believe that's what I said yesterday. But that's not particularly relevant to this report.
Q. Okay. Well, I just want to unpack that a little bit.
Do you believe that the warning letter rendered all of Baxter's products adulterated retrospectively?
MR. DAVIS: Object to form and vague and ambiguous as to retrospectively.
You can answer.
THE WITNESS: You're asking me to give an opinion on something that happened 22 years ago. I don't recall.
Q. (BY MR. STOY) Okay. Well, you already gave the opinion and you've restated it this morning that you believe that that warning letter rendered all of Baxter's products adulterated.
A. No, I did not say that.
Q. What did you say?
A. We're talking about that specific facility.
Q. Right. I'm sorry. At that specific facility, right?

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A. Right. I believe that's what the warning letter probably said so...
Q. Would that warning letter have rendered products at other Baxter facilities adulterated?
A. I don't recall the exact circumstances of that letter. I don't know and I don't want to speak to something that happened 22 years ago.
MR. DAVIS: Frank, let me just place a continuing objection on this. This was covered at length yesterday. I don't think it's appropriate to -- for multiple attorneys to recover the same ground over and over again.
MR. STOY: Well, I'm asking different questions, John. But your -- your objection is noted.
Q. (BY MR. STOY) I want to understand, though, do -- do you believe that the warning letter -- you're not sure about retrospectively. What about -- did that warning letter to Baxter render products manufactured at that facility prospectively adulterated?
MR. DAVIS: Object to form. Again, vague and ambiguous as to what you mean by "prospectively."
You can answer it if you understand it.
THE WITNESS: I don't recall. We're going back some 22 years ago. We'd have to go back -- I don't even have those files so I don't recall exactly what the

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situation was back then.
Q. (BY MR. STOY) Do you know if Baxter took any products off the market as a result of that warning letter?
A. I don't recall what Baxter did back in those days. I don't know. I'm sure -- I'm sure if we wanted to research that, we could determine whether, in fact, that happened. But 22 years ago, I don't recall.
Q. Can you explain to me how it would be that the FDA could permit adulterated products to be sold in the United States under the FDCA?
A. No. I -- I'm not -- I'm not going to answer that because I don't know because you're asking me to speak for the FDA again, and I can't speak for the FDA. Every circumstance would be different, and I'm not going to speak for the FDA.
Q. But you've quoted the FDA extensively in your report, right?
A. I quoted the FDA versus the investigator's statements and the EIRs that I referenced.
Q. And you can't speak to the truth of those statements one way or the other, right?
MR. DAVIS: Object to form.
THE WITNESS: I have no reason to believe that any statements that were made in the EIRs are

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incorrect or misstated.
Q. (BY MR. STOY) Right. You wouldn't have any reason to believe one way or the other, right?
A. Well, typically, in my experience the FDA when they put in quotes in the EIRs, they are very specific. And in all my years of experience, I've never seen those to be incorrect statements.
Q. So when you were at Baxter, you never disagreed with anything that the FDA put in a report?
A. That's not what I said.
Q. But that's my question.
A. Okay. So yes, we did disagree with the FDA on many occasions. So I want to clarify.
Q. I'm sorry. What's your answer?
A. So to clarify, sometimes we would get reports from the FDA that we did not agree with. We had discussions, and the FDA would respond. Sometimes the FDA agreed with us. Sometimes they didn't agree.
MR. STOY: Okay. I don't have any further questions for you, Mr. Quick. Thank you.
THE WITNESS: Thank you.
MR. DAVIS: Anybody else?
UNIDENTIFIED SPEAKER: Is attorney's counsel asking any questions.
UNIDENTIFIED SPEAKER: Let's give this a

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second because I do believe there are other counsel. Why don't we go off the record for a minute.

VIDEOGRAPHER: Off the record 10:00 a.m.

(Discussion off the record.)

VIDEOGRAPHER: We are back on the record -- we are back on the record at 10:18 a.m.

MR. DAVIS: Before you start, Steve, I just want to place on the record that a break was commenced at 10 o'clock a.m. and at the defendant's request and we're now back on the record almost 20 minutes later. Thanks. You can start.

EXAMINATION

Q. (BY MR. HUNCHUCK) Mr. Quick, my name Steven Hunchuck, and I'm going to ask you some questions regarding the Aurobindo defendants and your opinions about them.

If you could please pull up your report and turn to Paragraph 173.

A. Okay.

Q. Okay. At 173 it says, (Reading:) Aurobindo lacked competent quality management system in place to adequately investigate the root cause of the nitrosamine impurities.

THE REPORTER: Can you speak up or get closer to the mic?

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MR. DAVIS: Hey, Steven, we're having trouble hearing you. You're either muffled. It's like a combination of being muffled and low volume.

MR. HUNCHUCK: Sorry.

Q. (BY MR. HUNCHUCK) Looking at Paragraph 173 say, (Regarding:) Aurobindo lacked the competent quality management system in place to adequately investigate the root cause in nitrosamine impurities.

Can you please explain the basis for your statement "adequately investigated"?

A. The reason for this is the FDA warning letter that was issued --

Q. I cannot hear you, Mr. Quick.

MR. DAVIS: Can you not hear him, Steven?

MR. HUNCHUCK: Try again, please.

MR. DAVIS: Try your answer again, if you remember the question.

THE WITNESS: Yeah, I do. The reason for that statement is the FDA warning letter that was issued to the company relative to the issues in this case.

Q. (BY MR. HUNCHUCK) Do you know what steps Aurobindo took during that investigation?

A. It's hard to hear you.

MR. GOLDBERG: Counsel, just so you know, the audio sequence is very delayed. I know that the --

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MR. HUNCHUCK: I'm getting a delay on your end as well.

MR. GOLDBERG: I believe that the reporter had logged out during the break and logged back in. And I don't know if that had affected the audio or something. Maybe it would be a good idea to try and have her leave again and rejoin and maybe that will fix whatever issue we're having.

MR. HUNCHUCK: If you want to go off the record to fix this, we can do that.

VIDEOGRAPHER: Off the record 10:21 a m.

(Off the record.)

VIDEOGRAPHER: We are back on the record 10:26 a m.

Q. (BY MR. HUNCHUCK) Mr. Quick, going back to Paragraph 173, what -- what steps did Aurobindo take to investigate the route cause of the nitrosamine impurities?

A. Well, the reason -- the reason -- reason for my statement there was the fact that the company received the FDA warning letter. If, in fact, there was an adequate quality system -- quality adequate system placed, they probably wouldn't have received a warning letter. And having reviewed what Lantech did, it was very clear that the company did not do an adequate job

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of managing Lantech.

Q. Well, what steps did Aurobindo take to investigate the nitrosamine impurities?

A. I didn't review all the steps that they -- that they took or didn't take. But whatever they did was inadequate.

Q. So you're basing your opinion on the FDA warning letter then, correct?

A. I'm also basing it on the warning letter that went to Lantech after this occurred, and obviously, they had the same issues with Lantech which, in fact, the company should have known.

Q. Do you know what was missing from Aurobindo's investigation?

MR. DAVIS: Object to form.

THE WITNESS: Well, we could go through all the issues in the warning letter, all the issues in the warning letter to Lantech. Again --

Q. (BY MR. HUNCHUCK) Did you investigate its products from nitrosamines which is in your report?

MR. DAVIS: Is there a question there, Steven?

Q. (BY MR. STOY) Do you know what was missing from Aurobindo's investigation?

MR. DAVIS: Object to form. Objection,

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asked and answered.
THE WITNESS: So I did not go through all the specifics in terms of the specific investigations. But clearly the fact that all of this occurred at Lantech clearly indicates that they did not have proper investigations and/or proper review of Lantech.
Q. (BY MR. HUNCHUCK) Aurobindo's route synthesis was for its false API does not create nitrosamine; is that correct?
A. I --
MR. DAVIS: Object to form. Objection outside the scope.
THE WITNESS: You're hard to hear.
Q. (BY MR. HUNCHUCK) I can assure you I'm talking very loudly into my computer.
Are you aware that AB's route synthesis does not create nitrosamines?
MR. DAVIS: Object to form. Same objections as before.
THE WITNESS: Again, that's not a topic I particularly reviewed relative to my report. My report was addressing examples of CGMP deficiencies.
Q. (BY MR. HUNCHUCK) Okay. You testified yesterday that a manufacturer is supposed to characterize their impurities and know what they are; is

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that correct?
A. That's correct.
Q. Okay. If AB's route synthesis -- when I say "AB," I mean Aurobindo -- if AB's route synthesis does not create nitrosamines, how was AB supposed to determine that nitrosamines were present?
A. The --
MR. DAVIS: Object to form. You can answer.
THE WITNESS: The issue was the fact that these were not being properly investigated. It doesn't matter what they were. If they're unidentified peaks, they should be investigated to determine what they are.
Q. (BY MR. HUNCHUCK) And what steps do you -- does -- what steps should Aurobindo have taken to investigate those peaks that you referred to?
MR. DAVIS: Object to form and object, asked and answered already.
THE WITNESS: So clearly, Lantech was out of control. And the company was using Lantech for recycled solvents, and I mean, that came up I think in the warning letter that was issued to the company and also the warning letter that was issued to Lantech. Had they done a proper supplier evaluation and monitoring the supplier of recycled solvents, none of this probably

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would have happened.
Q. (BY MR. HUNCHUCK) Mr. Quick, I haven't gotten to overseeing Lantech. I'm still on the investigation of the nitrosamine.
How was Aurobindo to identify the nitrosamine in a product that does not synthesize nitrosamine?
MR. DAVIS: Object to form.
THE WITNESS: Well, the issue is the fact that the improper investigations is to determine what they were, what the impurities were.
Q. (BY MR. HUNCHUCK) But you don't know what steps Aurobindo took to investigate; is that correct?
A. All I know is what the FDA stated in the warning letter.
Q. Okay. Aurobindo did determine the root cause of its nitrosamine impurities; is that correct?
A. I'm not certain. Again, I'm only -- I have -- I have limited documents to look at relative to this particular situation, and I'm relying on the FDA's warning letter and also the warning letter that in circulation to Lantech.
Q. Are you aware that the nitrosamines -- excuse me. Strike that.
Are you aware that the amount of

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nitrosamines varied among the manufacturers' products?
MR. DAVIS: Object to form.
THE WITNESS: There may have been some variability, but that's not at all relevant to my report relevant to the CGMP deficiencies.
Q. (BY MR. HUNCHUCK) Do you have an understanding as to why there was variability in the nitrosamines?
A. I --
MR. DAVIS: Object to form. Objection, outside the scope.
THE WITNESS: That's not an area I reviewed. It was not part of the assignment relative to this report relative to the CGMP deficiencies. We may get into that later on if we go beyond this report to a merits report. But that has not been the scope of this report.
Q. (BY MR. HUNCHUCK) Do you know what manufacturer of valsartan products inspected their products for nitrosamines prior to 2018?
MR. DAVIS: Object -- sorry. No objection.
THE WITNESS: I missed the first part of that.
MR. DAVIS: Can you repeat the question, Steven?
Q. (BY MR. HUNCHUCK) Yes. Do you know which

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manufacturer of valsartan inspected products for nitrosamines prior to 2018?

MR. DAVIS: Objection -- object to the form and object to -- as vague and ambiguous as to the question.

You can answer.

THE WITNESS: So I'd have to go back and look at documents to see. I may be aware. It's not something I reviewed relative to this particular report.

Q. (BY MR. HUNCHUCK) All right. Please take a look at Paragraph 174 of your report.

A. Okay.

Q. It says here, the FDA told Aurobindo in a warning letter, et cetera, did you review the FDA's Form 483 from the AB site inspection?

A. I may have. I'm not certain. If I -- if I did, it would have been in one of the documents in my Exhibit A.

Q. Okay. Do you know whether Aurobindo responded in writing to the 483 before FDA issued its warning letter?

A. I'm having a difficult time hearing you. So I missed the first part of that.

MR. HUNCHUCK: Is there -- is there a way to turn up the volume of my voice in the room or?

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MR. DAVIS: Yeah, I think it's -- it's as high as it's going to go.

Q. (BY MR. HUNCHUCK) Okay. Mr. Quick, do you know whether Aurobindo responded in writing to the 483 before FDA issued its warning letter?

A. I don't know the answer to that question. My assumption would be that they most likely did, which was what most companies would do, but I don't know.

Q. Do you know whether Aurobindo informed FDA of its intent to evaluate the potential for key starting materials, other raw materials and solvents, to result in the presence NDMA and NDEA before the FDA issued its warning letter?

A. Again, I'm not sure I had those documents reviewed. So I'm not -- I don't know. I may have, but I don't know.

Q. Did you ask to see Aurobindo's response to the 483 report?

A. I don't believe I did. But I might have. But the relevant thing is, as I said before, I'm not looking at all the deficiencies, GMP deficiencies. I was just looking at examples, and these are the examples that I have for my report that apply to the entire class.

Q. And that -- that's exactly why I'm asking you about these examples you cited in your report.

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Do you know whether Aurobindo ever evaluated potential for key starting materials, other raw materials and solvents, to result in the presence of NDMA and NDEA?

MR. DAVIS: Object to form. Vague and ambiguous.

THE WITNESS: I have no idea whether they evaluated other things. Now again, my -- my focus was on the CGMP deficiencies. It wasn't what they may or may not have evaluated.

Q. (BY MR. HUNCHUCK) Do you know if -- strike that.

I would like to take a look at Paragraph 175. You say, (Reading:) The fact that Aurobindo could not even competently investigate the nitrosamine contamination once it became a focus of the FDA demonstrates that Aurobindo's quality management system had serious flaws and deficiencies.

Did I read that correctly?

MR. DAVIS: He's asking if you read Paragraph 175.

THE WITNESS: I did read it.

Q. (BY MR. HUNCHUCK) Okay. Can you please tell me what the serious flaws were?

A. The serious flaws were that the company

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qualified Lantech to recycle solvents without having done a proper investigation, didn't -- didn't understand what they were doing, and had they done that, had the quality management system been in place to do that, we probably wouldn't have had this situation.

Q. We're going -- we're going to get to Lantech. But I'm asking about Aurobindo's investigation that you cited in Paragraph 175.

So what were the serious flaws in Aurobindo's investigation? You say "serious flaws" and I would like to know what you mean by that.

MR. DAVIS: Object to form. Objection, mischaracterizing his report and the testimony.

You can answer.

THE WITNESS: Okay. The flaws -- the flaws were that they did not do a proper investigation relative to the issue. Had they done that, we would not have had the problem with Lantech. So I -- again, I'm -- I -- I am not going through an exhaustive analysis here. I'm just citing a couple of examples and this goes back -- I know you don't want to talk about Lantech here. But this goes back to the issue with Lantech and the recycled solvents.

Q. (BY MR. HUNCHUCK) Do you know how many lots of Aurobindo's products contained NDMA?

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A. I may have seen that, but that wasn't relevant to this report.
Q. Do you know the level of concentration of NDMA found in any of Aurobindo's lots?
A. I may have seen that someplace, but that was not relevant to this report.
Q. Would you agree that certain laws of Aurobindo's VCDs had concentrations of NDA below the FDA's acceptable intake level?
A. They may have. But again, that's not relevant. The real issue is the control. So if the company did not have adequate control or suppliers did not have adequate control and some lots had acceptable limits, others did not, would indicate there was a lack of control and consistency relative to the product.
Q. Mr. Quick, in your view, does the presence of a detectable about of nitrosamine in a VCD always demonstrate a failure to comply with the CGMP?
A. I did not opine on that. My point was that there with were deficiencies --
Q. I'm asking you -- I'm asking you --
MR. DAVIS: Don't cut the witness off, Steven.
Q. (BY MR. HUNCHUCK) My apologies. My apologies.
A. I did not render an opinion on that.

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Q. As you sit here today, in your view, does the presence of a detectable amount of nitrosamine in a VCD always demonstrate a failure to comply with a CGMP?
MR. DAVIS: Object to form. Objection, improper hypothetical.
THE WITNESS: Again, like I said, I did not look at that, I did not review that. If we want to do that in some further report, we can go down that report, but I did not go down that path in my report and I have not -- did not review that aspect.
Q. (BY MR. HUNCHUCK) Will you please take a look at Paragraph 72 of your report?
A. 72?
MR. DAVIS: 7-2.
Q. (BY MR. HUNCHUCK) 72, yes. It says, (Reading:) FDA expects drug manufacturers to test and compare recovered solvents to an established standard.
Did I read that correctly?
A. Right, you did.
Q. What was the solvent Aurobindo recovered?
MR. DAVIS: Object to form and object to the memory test that you're trying to use here.
THE WITNESS: So I probably saw that, but I don't recall that and that was not relevant to my report.

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Q. (BY MR. HUNCHUCK) What established standard applied for comparing Aurobindo's recovered solvent?
A. Well, it should be the established standard that the company had. My quote here from this -- in 72 is from the API process inspection manual.
Q. Do you know whether the test Aurobindo used would have detected the presence of nitrosamines?
MR. DAVIS: Object to form. Objection, outside the scope. He's not a process chemist.
You can try and answer if you -- if you want.
THE WITNESS: I don't have an answer for that because that's not an area that I reviewed and was not part of my report.
Q. (BY MR. HUNCHUCK) We can go back to the Aurobindo specific section. Please look at Paragraph 168.
A. Okay.
Q. You say, (Reading:) Lantech had not even been investigated by the FDA prior to 2018.
MR. DAVIS: Inspected I believe.
Q. (BY MR. HUNCHUCK) I'm sorry. Let me strike that.
You say, (Reading:) Lantech had not even been inspected by the FDA prior to 2018.

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Did I read that correctly?
A. You did.
Q. What is the basis for that opinion?
A. The basis is I don't -- I don't believe -- in fact, they had been inspected prior to that date. I believe they came in after this occurred.
Q. What is -- what assumption are you making for that belief?
MR. DAVIS: Object to form.
THE WITNESS: I -- I'm not quite certain where it came from, but I believe it to be factually correct.
Q. (BY MR. HUNCHUCK) That's -- that's my question. Where did that come from?
A. I don't recall at this point in time where it came from. But, I mean, that's something -- go ahead.
Q. Sorry. I didn't mean to interrupt you. Please go ahead.
A. So I believe that to be a statement of fact, but I'm not quite sure where that originated.
Q. Was Lantech licensed by the FDA?
MR. DAVIS: Object -- sorry. Object to form. Objection, vague and ambiguous.
You can answer.
THE WITNESS: Okay. The FDA does not

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license. The -- the firm has to have a drug establishment. They register as a drug establishment. The FDA does not license them.

Q. (BY MR. HUNCHUCK) Okay. In Paragraph -- can you please look at Paragraph 169?

A. Okay.

Q. You say, (Reading:) Had Aurobindo been properly overseeing Lantech Pharmaceuticals and conducting its appropriate due diligence, Aurobindo would have observed Lantech appeared to be cross-contaminating Aurobindo's solvents recovery activities with other manufacturers.

Did I read that correctly?

A. You did.

Q. Can you please describe Lantech's process for recovering solvents for Aurobindo?

MR. DAVIS: Objection, asked and answered. Objection, outside the scope. Objection, he's not a process chemist. I don't see where you're even trying to go with this, Steven.

You can answer if you want.

THE WITNESS: The issue was not how they do it. The issue was the cross-contamination.

Q. (BY MR. HUNCHUCK) You opined that Aurobindo failed to oversee its -- its solvent recovery vendor,

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and I'm trying to understand what you know about Lantech's solvent recovery methods to determine that Aurobindo failed to oversee it.

So my question is, please describe Lantech's process for recovering Aurobindo's solvent.

MR. DAVIS: Same objections.

THE WITNESS: So Lantech's processes are not relevant here. The fact is that they were not -- the proper oversight didn't exist, which appeared in the warning letters.

Q. (BY MR. HUNCHUCK) Where were the nitrosamines found at Lantech?

A. I don't recall where they were found.

MR. DAVIS: Object to form to that question also.

THE WITNESS: Again, my -- as I'll say again, my report was covering examples of CGMP deficiencies, and it was clear that the company did not have proper oversight over Lantech.

Q. (BY MR. HUNCHUCK) What is your understanding of what caused nitrosamines to be present on Lantech's equipment?

A. I did not get into that level of detail. The issue was that there was not proper oversight and this did, in fact, occur.

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Q. Looking back at Paragraph 169, you say "properly overseeing." Can you please tell me the basis for that statement?

A. Which -- which paragraph?

MR. DAVIS: Which paragraph, Steven?

MR. HUNCHUCK: 169.

MR. DAVIS: 169.

THE WITNESS: Okay. The basis for that is the FDA warning letter and also the deposition that I reference there.

Q. (BY MR. HUNCHUCK) Do you know what steps, if any, were taken to oversee Lantech's solvent recovery process?

A. I don't know what specific steps were taken. But whatever they were, they were not adequate.

Q. Why do you believe Aurobindo would have observed that Lantech appeared to be cross-contaminating?

A. That came out in the -- in the warning letters, and like I said before, if, in fact, the company had --had -- properly had oversight and audited and understood what Lantech was doing, the company should have been aware of what they were doing.

Q. Do you know what Lantech's solvent's recovery equipment looks like?

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MR. DAVIS: Objection to form. Objection, relevance.

THE WITNESS: I have no idea what their equipment looks like. I've never been to Lantech, so I've never seen it.

Q. (BY MR. HUNCHUCK) Do you -- in Paragraph 170 you say, (Reading:) Lantech's operations were so deficient that cross-contamination was occurring at least in four different ways.

What were the four different ways?

A. Well, the four different ways were described in the depositions, which if we want to pull those depositions up, we can look at those.

Q. Are you familiar with -- I'm going to butcher this name. Apologies. Are you familiar with Tree Can't (phonetic) Road Lines?

A. I didn't hear that.

MR. DAVIS: Can you -- can you repeat the question?

Q. (BY MR. HUNCHUCK) Are you familiar with Tree Can't (phonetic) Road Lines, the trucking company, Tree Can't Road Lines?

A. Am I familiar with them? I don't believe so.

Q. Are you familiar with Jaganat Road Lines?

MR. DAVIS: Objection, relevance.

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You can answer.
THE WITNESS: I don't believe I am.
Q. (BY MR. HUNCHUCK) Have you ever seen Lantech -- strike that.
If we look at Paragraph 171, you say, (Reading:) Aurobindo's chief quality officer, Dr. Ambati Rama Mohana Rao, would agree that Lantech's equipment is being uncleaned.
Do you know what equipment Mr. Rao was referring to?
A. I don't know specifically what equipment he was referring to. This comes from the deposition.
Q. Do you have an understanding as to what he meant by saying "unclean"?
A. Well, we'd have to go back to the deposition if we want to do that, and we could discuss that. But I -- just looking at this today, I'm not sure. I mean, the fact is it wasn't. So...
Q. Why do you say that?
A. Because there was cross-contamination.
Q. Do you know how many lots of Aurobindo's products were contaminated by unclean equipment?
MR. DAVIS: Objection, asked and answered.
THE WITNESS: I -- I don't know how many lots were contaminated. Again, that's not relevant to

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the CGMP deficiencies. The CGMP deficiency would -- would pertain to whether they had contaminated a product or not. So how many lots would not be relevant to this.
Q. (BY MR. HUNCHUCK) Are you aware that not all of Aurobindo's lots were recalled?
A. I'm not -- I'm not certain how many lots were recalled or whether they weren't recalled. But again, that's not relevant to the CGMP deficiencies that I found. And again, I state those were just examples.
Q. Are you aware that certain consumers of Aurobindo's valsartan containing drugs did not consume any nitrosamines?
MR. DAVIS: Objection, assumes facts not in evidence.
THE WITNESS: Again, I'm not aware of that, and again, it's not relevant to the report that I wrote.
Q. (BY MR. HUNCHUCK) Okay. In Paragraph 172 you say, (Reading:) Had Aurobindo done even a minimal amount of due diligence, it could have discovered these deficiencies for itself in any of the years prior to 2019.
What was necessary to discover the presence of nitrosamines before 2019?
A. So the paragraph talks about the deficiencies. And my point earlier had the company done an adequate

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job of managing and had oversight of Lantech, they would have been there, they would under covered the same kinds of things that the FDA did before the FDA inspected. So they should have been able to have found whatever the FDA found.
Q. Do you know whether any BCD manufacturers, API, or API manufacturers were testifying for nitrosamines prior to 2018?
MR. DAVIS: Objection, asked and answered. Frank asked that question in exactly the same verbiage.
THE WITNESS: So we'd have to go back and review the documents relative to that particular point. And again, that was not relevant to my report.
MR. HUNCHUCK: That's all the questions I have, Mr. Quick.
THE WITNESS: Thank you.
EXAMINATION
Q. (BY MR. ABRAHAM) Morning, sir. My name is Eric Abraham. Can you hear me?
A. I can hear you, yes.
Q. Great. I'm going to be asking you some questions next. I'm at the law firm of Hill Wallack in Princeton, New Jersey, and I represent the Hetero Labs and Hetero Drugs, defendants in this case. All right?
A. All right.

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Q. Do you still -- still have your report in front of you?
A. I do.
Q. Okay. Great.
Please tell me your understanding of the role, if any, that Hetero Labs played in the supply of valsartan into the United States.
MR. DAVIS: Object to form.
THE WITNESS: We'd have to go back -- as we talked about, there's been a number of entities here. We'd have to go back and review those documents. That was not the subject of my report. My subject of my report is what I have on Page 35 of the report.
Q. (BY MR. ABRAHAM) Okay. Let me ask it different.
Do you know whether Hetero Labs was an API manufacturer or a finish dose manufacturer of valsartan?
A. I believe that they're an API manufacturer.
Q. And do you think that they were a finished dose manufacturer? Do you know?
A. I'm not -- they may be. I'm not sure.
Q. Okay.
A. I would have to go back -- I would have to go back and review the documents. Again, that's not something I opined in the -- in the -- my document, my

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report.
Q. Okay. And how about Hetero Drugs, was Hetero Drugs an API manufacturer; do you know?
A. I thought I just -- just answered that.
Q. Okay. Do you know the difference between Hetero Drugs and Hetero Labs as corporate entities?
A. I -- I have not studied the corporate structure of the company.
Q. Okay. Do you know which one manufactured API or which one manufactured finished dose of valsartan?
MR. DAVIS: Objection, asked and answered. He says he hasn't studied the corporate structure of Hetero.
MR. ABRAHAM: Counsel, please don't answer for the witness.
Q. (BY MR. ABRAHAM) Can you tell me what the difference is between Hetero Drugs and Hetero Labs with respect to the manufacture of valsartan?
A. No. I cannot tell you the difference. If we went back and reviewed some of the documents, maybe I could, but that was not the subject of my report.
Q. Do you know what manufacturing facility, either Hetero Drugs or Hetero Labs, produced the valsartan APIN?
A. Which facility?

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Q. Yes, sir.
A. I'm not certain. But that -- I'm sure that was probably on the 43. I -- that wasn't relevant, this particular document, to put which facility.
Q. Sir, I don't want to hear about your position about what's relevant --
MR. DAVIS: He's entitled -- hang on, Eric, he's entitled to his testimony.
MR. ABRAHAM: Don't interrupt me. I have very little time. Don't interrupt me.
Q. (BY MR. ABRAHAM) My next question, sir: Do you know what Hetero facility manufactured the valsartan finished dose?
A. I probably do. Okay. Well -- the finished dose, I'm not certain.
Q. Okay. Now, if I look at your report, it looks to me like Paragraphs 176 through 186 are the paragraphs that are specific to Hetero; is that correct?
A. That is correct.
Q. You offered no opinion as to any alleged failure by Hetero to conduct a risk assessment associated with any manufacturing change for valsartan and API, correct?
MR. DAVIS: Object to form.
THE WITNESS: Let me just look back at the

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report. I don't believe that was one of the issues that I looked at here. Again, my --
Q. (BY MR. ABRAHAM) Okay.
A. -- as I said before --
MR. DAVIS: Hey, hey, Eric, let him finish his answer. Thank you.
MR. ABRAHAM: Answer the question. Thank you very much.
MR. DAVIS: Hang on. Before you move on, you've got to let the witness finish his answer. You cannot cut him off mid sentence. Thank you.
MR. ABRAHAM: John, please, stop.
Q. (BY MR. ABRAHAM) Sir, you haven't offered any opinion as to any failure by Hetero to assess deviations or unknown peaks or aberrate, correct?
A. That's correct. I only offered the opinions that I offered relevant to the specific deficiencies that are in this report. And again, I cite those as being examples. There may be others.
Q. And you offered no opinion about any failure by Hetero to adequately validate the valsartan manufacturing process change, correct?
A. Again, as I said, I only offered opinions on specific examples. It was not an exhaustive analysis of the issues.

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Q. So your expert report focused on two Form 483s that were issued to Hetero, correct?
A. I believe that to be the case. But we'd have to go back and --
Q. Those are the only things that you footnoted --
MR. DAVIS: Eric, let him finish his answer before moving onto your next question.
THE WITNESS: I believe that to be the case. The documents that I referenced are the ones in the footnotes at the bottom of the page.
Q. (BY MR. ABRAHAM) Right. And those -- the only footnotes are to the two Form 483s, right?
A. I believe that to be the case.
Q. Okay. I have emailed to your counsel, Ms. Hilton, copies of those two Form 483s. So if I could ask her to please hand those to you so that way if we need to refer to them during the questioning, you'll have them. Okay?
MR. DAVIS: Sure. I am handing them to the court reporter to be marked as exhibits.
MR. ABRAHAM: Great. And if the court reporter could just mark the March 2018 Form 483 and the September 28 Form 483 and just let me know what numbers you affix to those.
MR. DAVIS: Okay. The March one will

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first.
(Exhibits No. 30 and 31 were marked.)
MR. DAVIS: For the record, the witness has the March 483 as Exhibit 30 and the September as Exhibit 31.
Q. (BY MR. ABRAHAM) Great. Sir, if you could just confirm for me, do you see Bates numbers on the bottom of Exhibit 30? It should say Hetero USA with some numbers?
A. I do.
Q. Okay. It's Hetero USA151204 on the first page?
A. I do.
Q. Okay. And it goes through -- the last number ends with the Bates number 7, correct?
A. Yes, that's correct.
Q. Okay. And then for Exhibit 31 it's got the Bates number HLL446173 on the bottom right corner, right?
A. That's correct.
Q. Okay. And the very last page, it ends with 446176, correct?
A. 179?
Q. Oh, it goes through 179? Okay.
A. Yes.
Q. Thank you.

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These Form 483s were issued by the FDA at Hetero in conclusion of facility inspections that are referenced in the upper right-hand corner of Form 483, right?
A. I missed the last part of that.
Q. The dates of inspection for each Form 483 are notated in the upper right-hand corner, correct?
A. That's correct.
Q. So those inspections occurred in late February and early March of 2018 and then a second series of inspections in September of 2018; is that correct?
A. That's correct.
Q. Other than these two Form 483s, did you rely on anything else to reach your conclusions that you reached as against Hetero in your declaration that's marked as Exhibit 6?
A. Again, I'd have to go back and look at all these footnotes to make sure that these footnotes that I reference here didn't include any other documents. But I'm not certain because we haven't -- I haven't pulled those up.
Q. Okay. Did you review any of the FDA's establishment inspection reports for the Hetero manufacturing facility that's the subject of Exhibit 30, the Form 483 from -- from March 2018?

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A. I don't believe that I had those.
Q. Of the -- the February and March of 2018 inspection, that occurred a few months before the manufacture of the valsartan by Hetero that allegedly contained the NDMA impurity; is that correct?
A. If you're asking did this occur before the ZHP in the situation of June of 2018, is that what you're asking?
Q. No, my question was specifically to Hetero. Not ZHP, sir.
A. Okay.
MR. DAVIS: Perhaps you can repeat the question.
Q. (BY MR. ABRAHAM) My question is whether this inspection that's referenced in Exhibit 30 took place before the manufacture of allegedly impure valsartan by Hetero.
MR. DAVIS: Object to form.
Q. (BY MR. ABRAHAM) Do you know?
A. I'm not certain I really understand what you're asking.
Q. Okay. If you don't understand my question, say so.
Do you know when it is that Hetero is alleged to have manufactured valsartan with an NDMA

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impurity present?
A. I'm not certain. There may have been documents, but I'm just not certain here today.
Q. Okay. Did you evaluate or consider whether FDA had determined that the Hetero manufacturing facility was in an acceptable state of compliance with CGMP as of February and March of 2018?
A. As you indicated, the documents that I reviewed were the FDA 483 reports.
Q. I understand that. But I want to know whether you did anything to determine whether FDA had determined that the facility was in an acceptable state of compliance with CGMP as of the February and March 2018 timeframe?
A. I'm not sure there are any other documents to review. Had I -- if the documents were there, I'd be glad to review them.
Q. I'm not asking you to do something now. I'm wondering what you did to form your opinion. In other words, did you or did you not determine whether FDA had reached the conclusion about whether the facility subject to Exhibit 30 was in compliance with CGMP as of February and March 2018? If you did, you did. If you didn't, you didn't. Just tell me.
A. So in order to do that, we probably would have

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had to seen the EIRs from prior inspections where they probably would state that. I have not seen those.
Q. Okay. So you didn't look at the EIRs either before or after March 2018 for Hetero, is that fair?
A. Well, it's fair, but I don't think they were provided. Had they been provided, I would have reviewed them.
Q. Okay. But they weren't provided by the lawyers who retained you, right?
A. Again, I'm not certain. If they have them, they may have been provided, but I just don't recall reviewing those.
Q. Okay. So in other words, the lawyers that retained you may have made a choice not to share those documents?
MR. DAVIS: Objection, that mischaracterizes his testimony.
THE WITNESS: That's not what I said.
Q. (BY MR. ABRAHAM) Okay. You told me that you hadn't been provided with those documents, correct?
A. I'm not even sure that I asked for them. So...
Q. Okay.
A. The bottom line is I have -- I have not seen those. To answer your question whether it'd been in compliance, I don't know because I haven't seen the

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document that would say one way or the other.
Q. And you didn't ask for them, correct?
A. Well, I don't -- I don't know. I would have to go back and see what it asked for originally.
Q. Okay. And you weren't provided them. We can agree on that?
A. Well, I don't know. I am not sure what was provide and what wasn't. I'd have to go back and check.
Q. Okay. They're not listed on your exhibit to your expert report as materials that you reviewed in connection with the report, correct?
A. If they're not there, then I did not review them.
Q. Okay. Did you determine the existence of any inspectional classification for the Hetero unit that manufactured valsartan API in 2018 such as a no action indicated or a voluntary action indicated as of February or March of 2018?
A. I did not review that. But if I were to pursue this beyond this, I -- that's one of the things that I would do. Again, as I said, my list of examples were only examples. They're not exhaustive in terms of the situation.
Q. Okay. And did you review any correspondence to Hetero from FDA that followed the February or March 2018

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inspection?
A. I don't believe I've seen that.
Q. Isn't the normal process for the recipient of a Form 483 to respond?
A. It is.
Q. Do you know whether Hetero responded to the Form 483s that were issued in March and September of 2018?
A. I don't know, but I assume they probably did. Most companies would respond.
Q. So in issuing your declaration, you didn't review any responses that Hetero may have made to those Form 483s, right?
A. Had I seen those, I would have reviewed them.
Q. Right. Did you ask for them?
A. I don't recall whether I asked for them or not.
Q. Wasn't it important to you to consider the responses of Hetero to the Form 483s issued in March and September of 2018 before you issued your declaration?
A. No. As I said before, my examples are only examples. It's not exhaustive. If this were a merits report, that's one thing I would absolutely do. But this is not a merits report. These are examples of CGMP deficiencies.
Q. Okay. But the Form 483s, they are not final

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agency action, right?
A. That is correct.
Q. Okay. So by forming your opinions based just upon the Form 483, isn't that sort of like only looking at one side of the equation and not the other in reaching your conclusion?
MR. DAVIS: Object to form. Object to the analogy.
THE WITNESS: I'm looking at what the FDA saw when they inspected the facility and what they had as observations. Again, I would review the other documents that you've referred to if this were to continue to a merits report, and I agree that those documents would be documents that I would review in that situation.
Q. (BY MR. ABRAHAM) Okay. And you offered your declaration without even reading the transcript of a single Hetero witness, correct?
A. I don't believe so.
Q. You don't believe so meaning you didn't review any Hetero Labs depositions, correct?
A. I don't believe that I did. I reviewed a number of documents. If they're not in my Exhibit A, then I did not review those.
Q. Okay. Let's talk about the Form 483s that you

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did cite in the report. And I'd like you to start with the March 2, 2018 Form 483 which we've marked as Exhibit 30. Do you have that in front of you?

A. I do.

Q. Great. Did you review any communication between Hetero and FDA regarding the manufacturing changes that allegedly gave rise to the NDMA purity of valsartan API?

A. I don't believe so. And if it's not referenced in my Exhibit A, then I probably did not review those.

Q. Okay. The March 2018 Form 483 identified five observations, correct?

A. Yes, there are five observations.

Q. And the Form 483 doesn't indicate that any of those five observations actually caused the NDMA impurity to arise in Hetero's valsartan API, correct?

A. Correct, but I wouldn't expect to see that anyway.

Q. You don't offer the opinion that any observations contained in the March 2018 Form 483 actually caused the alleged NDMA impurity to arise in Hetero's valsartan API, correct?

MR. DAVIS: Let me object just to -- in the sense that this document is heavily redacted.

But you can answer.

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THE WITNESS: Right. That was the point I was going to make as well. Most -- most of the observations are redacted to the point it's not clear. So I would assume the FDA did not make that connection, but it's not clear because of the redactions.

Q. (BY MR. ABRAHAM) Right. But you don't offer any opinion on the ultimate question of whether the observations contained in the Form 483 from March 2018 actually gave rise to the NDMA impurity in Hetero's valsartan, right?

A. That's correct. What I was offering opinions on was the CGMP compliance.

Q. Okay. So in other words, but -- but you don't connect the dots; in other words, you don't offer the opinion that any CGMP compliance issues that you identified for Hetero actually gave rise to the NDMA impurity allegedly found in Hetero valsartan, right?

A. Right. And that was outside the scope of the report. The report was identified examples of CGMP issues that might pertain to the class.

Q. Okay. As of March of 2018, there was no specification for NDMA levels in valsartan APIs; is that correct?

MR. DAVIS: Can you repeat that, Eric? I think we both missed that question.

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Q. (BY MR. ABRAHAM) Do you need it repeated, sir?

A. No. I heard the question. But my -- my -- my point was, what I was going to say is I'm not aware of specific dates relative to specifications or standards or whatever as it relates to this. I'd have to go back and -- I'd have to go back and review what those are. But again, that was not relevant to my report.

Q. As far as you know today, was there a USP monograph that required testing for NDMA as of March 2018?

MR. DAVIS: Object to form.

THE WITNESS: See, again, no. But again, I may have seen those documents but I -- those were not relevant to my report.

Q. (BY MR. ABRAHAM) Okay. Again, I'd like to look at the specifics briefly.

The first observation in the Exhibit 30 Form 483 relates to a thorough review of an unexplained discrepancy between a batch and some specs, correct?

A. Well, it's very heavily redacted. I mean, I can read what the unredacted part is.

Q. Right. And that's what the unredacted part says, right, the observation relates to an unexplained discrepancy, correct?

A. That's what -- that's what the -- that's what

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the top part of it says, and they go into the example, yes.

Q. Okay. And you don't offer the opinion that that discrepancy is what gave rise to the NDMA impurity alleged in the --

A. No.

Q. -- valsartan from Hetero, correct?

MR. DAVIS: Object to form.

THE WITNESS: No. And I stated this before, that was not --

Q. (BY MR. ABRAHAM) You've answered the question, sir. Thank you.

MR. DAVIS: Hey, Eric as a professional -- as a professional courtesy, you need to let the witness answer -- finish his answer.

MR. ABRAHAM: John, I have a very short amount of time.

MR. DAVIS: That does not -- that does not obviate --

MR. ABRAHAM: Don't interrupt me, John. Don't interrupt me. He answers the question --

MR. DAVIS: You need to not interrupt the witness, Eric.

Q. (BY MR. ABRAHAM) Sir, I would like to draw your attention to observation No. 2. Observation No. 2

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relates to responsibilities and procedures applicable for the quality control unit not being followed. Do you see that?
A. I see that.
Q. And you don't offer the opinion that that's what caused the NDMA to arise in Hetero's valsartan, right?
A. No, it goes back to the questions I answered previously --
Q. Okay. Thank you.
MR. DAVIS: Let me just -- I'm going to place a formal running objection on the record to the continued interrupting of the witness before he finishes his answers.
MR. ABRAHAM: And I'm going to place an objection to the witness's having to answer the questions by giving a speech. So please just confine yourself to answering my question. You can talk to your lawyer afterwards and tell him whatever else you want to tell him.
Q. (BY MR. ABRAHAM) I would like to draw your attention, please, to the third observation. This relates to some allegations regarding the lack of training and experience for some employees involved in the processing holding and testing the drug problem,

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correct?
A. Correct.
Q. So this has to do with some interviews that were conducted by QC personnel within the manufacturing unit by FDA's inspector, right?
A. It appears to be the case.
Q. And you don't offer the opinion that that's what caused the NDMA to arise allegedly, right?
A. Same answer as I have given before. I don't offer that for any of these.
Q. Thank you. Observation No. 4 has to do with the equipment used in the production about being maintained in proper conditions. Do you see that?
A. I do see that.
Q. Okay. And same answer as before, in other words, you didn't offer any opinion that this is what caused the NDMA to arise, correct?
A. That is correct.
Q. Okay. And the last observation has to do with storage of glassware in a storage area, right?
A. Right.
Q. Okay. And same answer, that's not what gave rise -- or you don't offer the opinion that that's what gave rise to the NDMA --
MR. DAVIS: Before the witness answers, let

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me just place an objection. This is outside the scope. He's not offering any opinion about how nitrosamine is actually formed in these products.
You can answer.
THE WITNESS: Again, same answer as before.
Q. (BY MR. ABRAHAM) Thank you. Now I would like to turn your attention, please, to Exhibit 31. That's the September 2018 Form 483. Do you have that in front of you, sir?
A. I do.
Q. Okay. Do you understand that this Form 483 occurred in the month or so after FDA's recall of Hetero's valsartan?
A. So I see it's September. Relative to that sequence of timing, I'm not certain.
Q. So you don't know the dates when Hetero's valsartan was recalled; is that correct?
A. Well, I probably do. I probably looked at it. But I don't recall those dates in conjunction with this particular inspection. So I don't want to give an answer without going back and checking the exact dates.
Q. Okay. What would you go back and check?
A. Well, the dates that -- you asked the timing relative to the recall, I'd have to go back and determine when the recall was, and then I could answer

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your question about whether it was before or after.
Q. Well, I want to know is that something that you think you already know the answer to and you just forgot it or that's an answer you would have to go learn?
A. It wasn't relevant to my report in terms of CGMP deficiencies. So if you're asking me that question, I need go back and determine when the recall was, and I could determine whether this was before or after. That's the question you're asking me.
Q. Okay. Let's look at Exhibit 31. This offers four observations relative to the inspection that was conducted September 17the through the 28th, correct?
A. Yes, sir, four observations.
Q. Okay. And the Form 483 that's marked as Exhibit 31 that doesn't indicate that any of those four observations actually caused the NDMA impurity to arise in Hetero's valsartan API, correct?
MR. DAVIS: Do you need a few moments to review the document?
THE WITNESS: I probably need to read this if you want me the answer that.
Q. (BY MR. ABRAHAM) Well, you read it before you offered your opinion, right?
A. That's been some time ago.
Q. But you did read it, right?

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A. I did.
Q. Okay. And in your expert report you wrote that none of the observations -- well, you didn't offer the opinion that any of the observations contained in the September 28th Form 483 actually caused the alleged NDMA impurity to arise, correct?
A. That's correct. And that was not within the scope of my report.
Q. Okay. So you stand by that opinion, correct?
A. I do.
Q. Okay. Let's look at the specific observations. Observation No. 1 relates to the quality control unit failed to perform a thorough investigation. Do you see that?
A. I do.
Q. That's an observation that relates to the investigation performed by Hetero after the impurity was discovered allegedly in Hetero's product, correct?
MR. DAVIS: Do you want -- you're asking, Eric, about two-and-a-half pages of single space type. I think the witness --
MR. ABRAHAM: John, if you want to make an objection, make it. Okay. He just told me he reviewed this document in preparation for his deposition. I would just like to confirm his understanding.

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MR. DAVIS: Do you need a few moments to read Observation 1?
(Cross-talk.)
THE WITNESS: If you want me to answer that question, I need to review this today because you're asking me a question specifically about the 483.
Q. (BY MR. ABRAHAM) Okay. Great. Go ahead. And let me know when you're done.
A. Okay.
MR. GOLDBERG: May I suggest that we go off the record because --
MR. ABRAHAM: No, Seth, you may not suggest that because y'all pitched a fit about that when your witnesses were spending 20 minutes reading a document. So we will not go off the record.
Q. (BY MR. ABRAHAM) You know what? I'll ask another question because I don't want to waste the time it will take you to refresh you -- yourself on what the contents of that document are.
Are you familiar with what FDA action resulted from the March 2018 or the September 2018 483's issue to Hetero?
A. I've not seen the actions. If there were any actions, I've not seen those.
Q. So you don't if there was an NAI issue or a VAI

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or an OAI?
A. I'm not certain. I've not reviewed those.
Q. Okay. Are you aware of any official action that was taken by FDA as a result of the Form 483s that you relied on in this report?
A. Again, I did not review those.
Q. So you don't know if there's a warning letter?
MR. DAVIS: Eric, the -- Eric, the videographer has indicated that he needs to go off the record to change the tape.
MR. ABRAHAM: Okay. We can go off the record and do that. Thank you.
VIDEOGRAPHER: Off the record 11:20 a m.
(Off the record.)
VIDEOGRAPHER: We are back on the record 11:24 a m.
MR. DAVIS: For the record, there is 54 minutes remaining.
MR. ABRAHAM: Thank you. Just to the videographer, our witness is very blurry. Okay. There you go. Thank you.
Q. (BY MR. ABRAHAM) Sir, I just have a few more questions, and I appreciate your patience.
Are you aware of any warning letter or import ban that was issued by FDA to Hetero as a result

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of the Form 483s that we've been reviewing this morning?
A. I'm not aware of any.
Q. Any seizure or regulatory meeting or recommendations to cease manufacturing?
A. I'm not aware of any.
Q. Okay. Are you aware of any corrective and preventive actions or cappas (phonetic) relating to the observations of the two Form 483s that we've been discussing?
A. I'm not aware of any because I have not seen what the company may have done relative to the 483.
Q. Okay. So did you review any cappas that were initiated in connection with the Form 483s that we've been discussing?
A. I would -- if I had seen them, I would review them.
Q. Did you ask to review them?
A. I didn't ask to review them because I didn't know any had been generated.
MR. ABRAHAM: Okay. Okay. I am concluded with my questions. I appreciate your patience, sir.
THE WITNESS: Thank you.
MR. ABRAHAM: What I would like to do is ask that we take a very short break so that I can confer with my co-counsel. I think we have one questioning

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lawyer left to go.
John, can we take a very short break?
MR. DAVIS: Okay. All right.
VIDEOGRAPHER: Off the record 11:25 a m.
(Brief recess.)
VIDEOGRAPHER: Back on the record. The time is 11:34 a m.
EXAMINATION
Q. (BY MS. NAGLE) Hi, Mr. Quick. My name is Brittney Nagle, and I represent Torrent Pharmaceuticals, Ltd. and Torrent Pharma, Inc.
Have you ever heard -- and I may refer to them together as Torrent. Is that fair?
A. You're asking if I've heard of Torrent?
Q. I was asking for clarification. When I refer to Torrent, I'm referring to those two entities. Okay?
A. What were the two entities again?
Q. Torrent Pharmaceuticals, Ltd. and Torrent Pharma, Inc.
A. I would generally just refer to the one.
Q. By "the one" do you mean Torrent Pharmaceuticals, Ltd.?
A. I would not have made a distinction is what I'm saying.
Q. Okay. Well, you understand there's two

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different entities?
A. Okay.
Q. All right. Do you have any understanding about the difference between the two entities?
MR. DAVIS: Object to form.
THE WITNESS: I may, but that was not part of my review.
Q. (BY MS. NAGLE) Okay. Had you -- have ever heard of Torrent prior to being engaged in this matter?
A. I'm sure I have.
Q. Have you ever done any work for Torrent?
A. No, I have not.
Q. So safe to say you've never physically been to a Torrent facility?
A. I don't believe so unless there was some sort of an acquisition that Torrent had and I might have been in a facility where they acquired. But I'm not aware of that.
Q. Are you aware of any instances where you've been adverse to Torrent in another engagement?
MR. DAVIS: Object to form.
You can answer.
THE WITNESS: No. I'm sorry. No.
Q. (BY MS. NAGLE) So prior to your engagement, did you have any understanding about the types of

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products that Torrent manufactures?
A. Prior to the engagement? I may have, but it's not something I had particularly understood or had an interest to understand.
Q. Okay. So when you say you may have, do you mean just in your familiarity with the pharmaceutical industry?
A. Well, what I'm saying is you asked the question about Torrent's products prior to this engagement. It's very possible that I may have. I don't recall.
Q. Okay. So sitting here today, you don't recall knowing anything about what kind of products Torrent manufactures prior to being engaged in this matter?
A. That's not exactly what I said. I may have, but I'm not aware that I was.
Q. Okay. And prior to this engagement, you didn't have any understanding of the relationship between Torrent and any of its suppliers, correct?
MR. DAVIS: Object to form.
THE WITNESS: I don't believe so.
Q. (BY MS. NAGLE) Okay. Prior to your engagement, you hadn't done any analysis of Torrent's quality assurance program, correct?
A. I don't believe so unless it was in connection with something else unrelated to this. But I don't

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believe so.
Q. Okay. So there's a possibility, but sitting here today, you can't think of specifically any engagement that would have required you to -- to know anything about Torrent's quality assurance program?
A. I don't believe so, as I said.
Q. Okay. So -- so as far as you know, as far as you can remember, the totality of your understanding of Torrent's quality assurance process is based on documents that you've reviewed in connection with this engagement, correct?
MR. DAVIS: Object to form.
THE WITNESS: I believe so.
Q. (BY MS. NAGLE) Okay. And your understanding of the relationship between Torrent and ZHP is based entirely on the documents you reviewed in connection with this engagement, correct?
A. That is correct.
Q. So in your report, looking specifically at Paragraph 157, you reached the conclusion that Torrent failed to diligently inspect the manufacturing process prior to retaining ZHP as its API manufacturer, right?
A. Right.
Q. What do you mean comprehensive chemical analysis?

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MR. DAVIS: Where are you referring to, Brittney?
THE WITNESS: Can you refer me to the paragraph you're talking from?
Q. (BY MS. NAGLE) Oh, sorry. I -- I misquoted part of your report. I apologize.
In Paragraph 159, that's -- that's where I'm reading that from. I apologize.
So in Paragraph 159 you wrote, (Reading:) Torrent also made no inquiries into the manufacturing process uses -- I think that should be used by ZHP and failed to conduct a comprehensive chemical analysis.
Do you see that?
A. I do see that.
Q. Can you tell me what you meant by "comprehensive chemical analysis"?
A. Well, it goes to some of the other aspects of this section on Torrent, and it relates to the depositions that I reviewed.
Q. Okay. What would you require for a comprehensive chemical analysis?
A. I wouldn't require anything. I'm just saying I don't believe that they did.
Q. What is the basis for that?
A. I'm just saying based on the depositions that I

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reference in this report, I don't believe that they did an adequate chemical analysis.
Q. Okay. And so I'm asking, well, if you believe it was inadequate, what would you have wanted them to do?
A. Okay. As we -- if we can look at Paragraph 161, Torrent, as indicated, had they known of the chemicals used in the manufacturing process, the chemical analysis revealed what I said in there, had they done that, they would have been able to determine this. So they should -- they should have known what these chemicals were that were being used in the ZHP process.
Q. So, Mr. Quick, you're aware that Torrent is a finish dose manufacturer, correct?
A. Correct.
Q. And as a finish dose manufacturer, you're aware that Torrent does not get full access to the DMF for valsartan API, correct?
MR. DAVIS: Object to form. Object to mischaracterization of -- of the -- well, just object to form.
You can answer.
THE WITNESS: So the point would be that I believe Torrent should thoroughly understand the process

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that ZHP used to make the product that they are requiring from ZHP, however they do it, whether it's DMF or on-site visits looking at the documents, whatever.
Q. (BY MS. NAGLE) Well, Mr. Quick, you understand that -- that the process API -- the process ZHP uses to manufacture its API contains proprietary information, correct?
A. I hear what you said. But my point is that the drug manufacturer such as Torrent should have audited. They should have gotten complete information relative to how the product -- how the API is made.
Q. So it's your position that a finish dose manufacturer is entitled to all proprietary information for APIs that it sources?
MR. DAVIS: Object to form. Object to mischaracterizes his testimony.
You can answer.
THE WITNESS: So that's not what I said.
Q. (BY MS. NAGLE) But, Mr. Quick, you realize that Torrent isn't -- like, is not able to access all of the information regarding API that it sources?
MR. DAVIS: Object to form. Objection, asked and answered.
THE WITNESS: No, I'm not. But my point is that Torrent should have been able to understand exactly

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how to process was, and they should have asked for a number of documents to be able to understand the situation. So when you say they're not able to, I think they should have been able to.
Q. (BY MS. NAGLE) And how would you reconcile being able to do that if the information is proprietary information?
A. Well, you ask -- you ask ZHP for it and you say we need this to do a thorough evaluation of ZHP as part of a supplier audit, supplier qualification. And I'm sure there were confidentiality agreements between Torrent and ZHP such as ZHP could have provided the information that Torrent would ask for.
Q. Mr. Quick, you recognize that there's different testing done for API and for finish dose, correct?
A. Yes.
Q. And so a chemist trained to do testing for finish dose wouldn't necessarily know how to do testing for API, correct?
MR. DAVIS: Object -- object to the form. Calls for speculation. Incomplete hypothetical.
You can answer it.
THE WITNESS: I'm not even sure what you're trying to ask because it's not relevant. Maybe you can explain why you're asking that.

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Q. (BY MS. NAGLE) Okay. Mr. Quick, I want to talk a little bit about your materials relied upon.

So looking in Appendix A to your report, it looks like there are eight documents we see from Torrent and two deposition transcripts of Torrent employees. Do you see that?

A. I see that.

Q. And is this the totality of documents by Torrent you used in forming your opinions in your report?

A. The documents that I used were the documents I reference in Exhibit A.

Q. Okay. Any other documents?

A. Not that I'm aware of.

Q. In your report you also state that, (Reading:) The FDA also observed issues with Torrent's quality management activities related to the investigation of out-of-specification test results for their products and note that Torrent engaged Meridan consultants to assist, correct?

MR. DAVIS: Can you refer to the paragraph, Brittany?

Q. (BY MS. NAGLE) Sure. And that -- that's in Paragraph 163 to 166, the section I'm going to be talking about.

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A. So is the question I'm aware? Yes, I am aware.

Q. Okay. And you note that Meridan found that 89 of 157 out-of-specification investigations were non-compliant, right?

A. That's correct.

Q. Are you aware that none of those related to valsartan?

A. I'm not sure what they were related to, but it's not relevant to the report. The issue was whether they were CGMP compliance.

Q. Okay. So I guess taking a step back, the FDA warning letter that you're referring to is from October 2019, correct?

A. That's correct.

Q. So after the date of the recall?

A. I'm assuming it's after the date of the recall.

Q. Okay. Mr. Quick, are you offering any opinions about Torrent at this point outside of what's contained in your report?

MR. DAVIS: Object -- object to form, vague and ambiguous.

You can answer.

THE WITNESS: Okay. The only opinions I'm offering at this time relative to this declaration are the opinions that I express in this report. Those are

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the only opinions. Were this to proceed to a merits report sometime in the future, I might offer different opinions. And if additional information became available, the opinions might differ. But again, it would apply to all users and all pills that were produced by the facility.

Q. (BY MS. NAGLE) Okay. So as of right now understanding those caveats, the only opinions you're offering with respect to Torrent are the ones listed here in your report, Paragraphs 157 to 166 there?

A. And again, that's -- that's true. And again, these were just examples.

Q. Okay. So Mr. Quick, yesterday you were shown your notice of deposition that included some document requests. Do you remember that?

A. I do.

Q. And I don't think we entered these. But do you -- do you recall that your counsel served responses and objections in response to those document requests?

A. I'm not -- I'm not certain what you're referring to.

Q. Okay.

A. We could pull that document up, if you'd like.

MS. NAGLE: Sure. So can someone please pass the witness what's marked Tab 2 -- or Tab 1, I

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apologize, that I uploaded it on Exhibit Share.

MR. DAVIS: Okay. Is this the -- the responses and objections that we served?

MS. NAGLE: Yeah, that's correct.

MR. DAVIS: Okay. I handing the --

MR. MILLER: Brittney, this is Bill Miller, the tech. Do you need me to mark that in Exhibit Share?

MS. NAGLE: Yes. Can you mark it? I believe we're up to 32, please.

MR. MILLER: 32, yes. Do you need it up on the screen or just a paper copy?

MS. NAGLE: I mean, paper copy is fine unless people on Zoom want to see it.

(Exhibit No. 32 was marked.)

MR. DAVIS: Do you -- do you want a few minutes to review it?

THE WITNESS: Sure. I -- I'm not certain if I have seen this or not. I can review it if you'd like?

MR. DAVIS: But there is no question pending.

He's ready for your question, Brittney.

Q. (BY MS. NAGLE) Okay. Mr. Quick, have you ever seen this document?

A. I'm not certain whether I have or not. I've

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seen a lot of documents. It's possible I may have seen it. I don't believe so, but I could have.
Q. Okay. I'm going to represent to you that this is the -- the formal response that your counsel made to our -- to those document requests that you saw yesterday and the notice of the deposition. Does that make sense?
A. That makes sense.
Q. Okay. And I want to direct your attention to -- I think it's page 5 of the document. It's Request No. 6 and the response to Request No. 6.
A. Okay.
Q. And Request No. 6 basically asks for the -- you know, your complete and entire file for this case. And it lays out some subcategories of documents. Do you see that?
A. I see it.
Q. Okay. And in the response, it goes on to the next page, your counsel says that they will produce a list of documents that were provided to you in your file.
MR. DAVIS: Is there a question?
Q. (BY MS. NAGLE) Do you see that?
A. Well, yeah, I can see that, yes.
Q. Okay. So can we look at Tab 2?
A. Tab 2.

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MS. NAGLE: And can that be marked, please, as Exhibit 33 or 34.
MR. DAVIS: Brittney, is this the list of documents?
MS. NAGLE: Yeah.
MR. DAVIS: Okay. I'm handing it to the court reporter.
(Exhibit No. 33 was marked.)
MR. DAVIS: The witness has the document, Brittney.
Q. (BY MS. NAGLE) Okay. Mr. Quick, do you recognize this document?
A. I'm not certain whether I've seen this document or not before.
Q. Okay. So I'm going to represent to you that this is the list of documents that your counsel provided in response to Request No. 6 --
A. Okay.
Q. -- about the complete file. Do you understand?
A. I understand.
Q. Okay. So I'm going to represent to you that if you compare this list against the list in Exhibit A of your report, the materials relied upon, there are 36 documents on that list you have that's marked, I believe, Exhibit 33 that do not appear in Exhibit A of

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your report. Do you understand?
A. I understand what you're saying.
Q. Okay. And 34 of 36 of those exhibits are Torrent exhibits. Okay?
A. Okay.
Q. So you were sent more materials related to Torrent than you ultimately relied upon, right?
MR. DAVIS: Object to -- object to form. And object to failure to lay a proper predicate to the question.
You can answer, though.
THE WITNESS: Yes, there are more documents here.
Q. (BY MS. NAGLE) Okay. Do you know why these additional documents were pro -- provided to you?
MR. DAVIS: I'm going to object. I'm going to counsel the witness not to disclose attorney work product and --
But you can answer with that cautionary instruction.
THE WITNESS: So I'd have to go back and review each and every one of these to understand. So I'm not certain just by looking at this list.
Q. (BY MS. NAGLE) Okay. So do you have any reason why you chose not to rely on these documents that

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were provided?
MR. DAVIS: Object to form. Same instruction.
THE WITNESS: Well, my --
MR. DAVIS: You can answer.
THE WITNESS: Okay. So I -- the documents that I relied on for my report are the documents that I reviewed and are Exhibit A. That's -- those are the documents I relied on for my report. So there may have been other documents that I didn't rely on these for my report.
Q. (BY MS. NAGLE) Okay. And I'm just trying to understand why -- why you excluded these 34 documents is all.
A. Well, okay. So I cannot answer that question without actually looking at those documents. But I'll go back to the comments I made before. My report only list examples. So there may be other examples that would be in these documents which might be in a report later, a merits report or something beyond that. But the documents that I relied on for my report are the documents that are in Exhibit A. So I'm not sure specifically why these additional documents were not relied on other than the fact I didn't need them relative to providing the examples that I have in my

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report.
Q. Okay. So the additional documents found on -- on this Exhibit 33 do not serve as a basis for any of the opinions contained in your report, correct?
MR. DAVIS: Object to form.
THE WITNESS: What I -- what I said was is that the documents that I relied on for my report are the ones that are Exhibit A.
Q. (BY MS. NAGLE) Okay. So you're not relying on any of these additional documents found in this exhibit?
A. If they're not in that Exhibit A, the answer is no.
MS. NAGLE: Okay. I have no further questions for you, Mr. Quick. Thank you. I think one of my colleagues has some clean-up questions, but appreciate your time today. Thank you.
THE WITNESS: All right. Thank you.
MS. ISIDRO: I have just a few questions briefly.
MR. DAVIS: Are you going to retread any ground or -- I don't think our protocol --
MS. ISIDRO: It's just -- just some follow-up based on the question today.
MR. DAVIS: I don't think our protocol is to have another bite at the apple here.

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MS. ISIDRO: It's just some brief follow-up based on the questions today.
MR. DAVIS: You passed the witness yesterday. I -- I am going to place an objection to this.
FURTHER EXAMINATION
Q. (BY MS. ISIDRO) Mr. Quick, do you recall being asked some questions this morning regarding a warning letter that you had received at -- during your time at Baxter, warning letter received by Baxter during your time there?
A. I do.
MR. DAVIS: I'm objecting to this. You covered this yesterday. You don't get another bite at the apple. I'm sorry.
MS. ISIDRO: We've noted your objection. Moving on.
Q. (BY MS. ISIDRO) And in addition to the warning letter that was discussed, during your time at Baxter, there were other inspections by FDA which led to observations about the inspected facilities; is that right?
A. Of the inspected facilities?
Q. Yes.
A. That's true, yes.

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Q. And some of those observations over the years related to issues about CGMP compliance?
A. They did.
Q. You testified that Baxter took the warning letter it received very seriously.
A. Yes.
MR. DAVIS: Asked and answered. Objection. This is covered in almost identically. You're just recovering the questions you asked yesterday.
Q. (BY MS. ISIDRO) You, likewise, took any additional CGMP observations that were received over the years seriously?
A. Yes.
MR. DAVIS: Same objection. This is an utter waste of time. It's running out the clock.
Q. (BY MS. ISIDRO) And you took appropriate corrective action?
A. Yes.
Q. In general, when Baxter received observations from the FDA related to CGMP issues, Baxter did not recall all product manufactured at the impact -- impacted facilities, correct?
MR. DAVIS: Object to form. Object to the extent it mischaracterizes his testimony from yesterday on which you asked these very questions. Objection,

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asked and answered.
THE WITNESS: So Baxter recalled the products from the -- appropriately should have been recalled.
Q. (BY MS. ISIDRO) But it did not recall every product from a particular facility every time that facility received a CGMP observation, correct?
A. No. That's correct.
MR. DAVIS: Same objection. I'm going to place a continuing objection to this. And this needs to be brief. This is -- you're recovering exactly what you covered yesterday. This is -- this is not proper.
Q. (BY MS. ISIDRO) In general, when Baxter received observations from the FDA related to CGMP issues, Baxter did not stop releasing all product from that impacted facility to the market, correct?
MR. DAVIS: Same objections.
THE WITNESS: Well, it depends. In some cases that might have occurred.
Q. (BY MS. ISIDRO) But it did not stop releasing all product from a particular facility every time that facility received any CGMP observation.
A. Well, there are some cases where it might have.
Q. But certainly not in every instance.
A. Of course not.

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MS. ISIDRO: I don't have any further questions at this time.
MR. DAVIS: Okay.
MS. ISIDRO: Oh, and just briefly, I'd like to mark for the record Exhibit -- I believe we're up to 34. It is a thumb drive containing all of the documents that were listed on Exhibit A to -- to Mr. Quick's report as well as the written responses and documents received in response to the notice of deposition.
MR. DAVIS: That's two separate things. Is that somehow -- I haven't seen how that's set forth on the jump drive.
MS. ISIDRO: It's not separated, but we can do that quickly and then mark it if that's -- if that's -- we discussed it yesterday and you didn't specify that, but I'm happy to do that now.
MR. DAVIS: I think maybe just for clarity sake let's do it.
MS. ISIDRO: Separate it?
MR. DAVIS: Yeah.
MS. ISIDRO: Sure, no problem.
(Exhibit No. 34 was marked.)
MS. ISIDRO: And it will be Exhibit 34, correct?

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MR. DAVIS: Yeah, 34 and then 30 -- yeah, 34. I mean, yeah, it can all be on that same jump drive, yeah.
MS. ISIDRO: We'll put it in two separate folders.
MR. DAVIS: Folders, yeah. Okay. No objection.
MR. KERNER: Anybody else on the Zoom have any questions?
MR. DAVIS: Okay. Not hearing anything, why don't we take like a one-minute break just to see how much time is left.
VIDEOGRAPHER: Off the record. The time is 12:01 p m.
(Brief recess.)
VIDEOGRAPHER: Back on the record. The time is 12:03 p m.

EXAMINATION

Q. (BY MR. DAVIS) Mr. Quick, the defendants have passed the witness after all questioning you for some amount of time. I just have a few redirect questions on my end.
So over the course of the past two days, you were shown a number of documents, correct?
A. Correct.

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Q. Some of those documents are listed in Exhibit A to your report or -- or in plaintiff's responses to the Request No. 6 that Ms. Nagle mentioned a few minutes ago, correct?
A. Correct.
Q. And then there's some amount of documents that were also shown you over the past couple of days that are not referenced in your report or in those responses, correct?
A. That's correct.
Q. Okay. Based on your review of those documents, is there anything in them that changes your core opinion in this declaration that appears at Paragraph 191 of your declaration?
MS. NAGLE: Object to form.
THE WITNESS: There is nothing in those documents that would change my opinion in 191.
Q. (BY MR. DAVIS) Okay. And what is that opinion in Paragraph 191?
A. I'll read it. It says, (Reading:) I do conclude that because of the nature of these deficiencies being high level corporate QA failings, the corporate quality assurance deficiencies described herein are the type of quality assurance activities that would have impacted each of the manufactures defendants'

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valsartan products equally and in the same manner.
Q. Okay. Thank you. Are you -- you're familiar that this litigation that you're testifying in today is part of what's called a multi-district litigation involving all these manufacture defendants whose attorneys questioned you today?
A. I am.
Q. Okay.
MR. ABRAHAM: John, this is Eric. I'm just going to place an objection on the record to the leading nature of your questions. It's improper.
MR. DAVIS: Thank you for the speaking objection, Eric and I'm allowed to do this for the introduction matters.
MR. ABRAHAM: Right. That's why I let it go for the first couple of questions. Your last question was improper.
MR. DAVIS: This is an introductory matter, Eric. Thank you.
MR. ABRAHAM: I move to strike the last answer and the last question.
MR. DAVIS: The judge has told us, the parties, numerous times, Eric, that he will not tolerate motions to strike as part of these depositions. So that's -- that's not proper. Okay.

MR. ABRAHAM: Right. He's also said no leading questions of your own witness. So you follow the rule, I'll follow the rule.

MR. DAVIS: Thank you.

Q. (BY MR. DAVIS) So Mr. Quick, what's your understanding of why these manufacture defendants are a part of this litigation?

MS. ISIDRO: Objection.

MR. ABRAHAM: Objection, form. No foundation.

MR. DAVIS: Let's not have multiple attorneys objecting. I think -- I think Nilda has it covered. She's present.

Q. (BY MR. DAVIS) okay. So what's your understanding, sir, of why these defendants are defendants in this litigation?

A. Because of the presence of nitrosamines in the finished drug products.

Q. Okay. And does the -- does the presence of those contaminants, nitrosamines as you said, is that one component of your opinion in Paragraph 28 of your declaration --

MS. ISIDRO: Objection, form.

Q. (BY MR. DAVIS) -- that the finished drug products involved in this litigation manufactured by the

defendants are adulterated?

A. Yes.

Q. Okay. Okay. Your -- your report has a number of exemplary sort of what you describe as examples of corporate level CGMP failures, in your words, that you provide as to each of the manufacture defendants; is that right?

A. That's right.

Q. Okay. How long have you been in the pharmaceutical and -- and general sort of FDA medical device industry, sir?

MS. ISIDRO: Objection.

THE WITNESS: Over 55 years.

Q. (BY MR. DAVIS) Okay. And your -- your observations in this declaration, are they based only on the documents and other materials or are they also based on those 55 years of experience that you have?

MS. ISIDRO: Objection, form.

THE WITNESS: They are based on my experience in addition to the documents.

MR. DAVIS: Thank you. No further questions.

Okay. Hearing nothing else, I think we can wrap it up and go off the record.

VIDEOGRAPHER: Okay. This concludes the

deposition of John Quick. Off the record at 12:08 p.m.

(Proceedings concluded at 12:09 p m.)

REPORTER'S CERTIFICATION
DEPOSITION OF JOHN QUICK
VOLUME 2 OF 2
TAKEN JANUARY 28, 2022

I, Janalyn Elkins, Certified Shorthand Reporter in and for the State of Texas, hereby certify to the following:

That the witness, JOHN QUICK, was duly sworn by the officer and that the transcript of the oral deposition is a true record of the testimony given by the witness;

That the original deposition was delivered to MS. NILDA ISIDRO;

That a copy of this certificate was served on all parties and/or the witness shown herein on _____.

I further certify that pursuant to FRCP No. 30(f)(i) that the signature of the deponent was requested by the deponent or a party before the completion of the deposition and that the signature is to be returned within 30 days from date of receipt of the transcript. If returned, the attached Changes and Signature Page contains any changes and the reasons therefor.

I further certify that I am neither counsel for, related to, nor employed by any of the parties in

the action in which this proceeding was taken, and further that I am not financially or otherwise interested in the outcome of the action.

Certified to by me this 6th day of February 2022.

JANALYN ELKINS
Texas CSR 3631
Expiration Date 1/31/2023
Veritext Legal Solutions
300 Throckmorton Street, Suite 1600
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John R. Davis
jdavis@slackdavis.com

February 7, 2022

RE: In Re: Valsartan, Losartan, Et Al v.
1/28/2022, John Quick (#5063421)

The above-referenced transcript is available for review.

Within the applicable timeframe, the witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason, on the attached Errata Sheet.

The witness should sign the Acknowledgment of Deponent and Errata and return to the deposing attorney. Copies should be sent to all counsel, and to Veritext at erratas-cs@veritext.com

Return completed errata within 30 days from receipt of testimony.

If the witness fails to do so within the time allotted, the transcript may be used as if signed.

Yours,
Veritext Legal Solutions

In Re: Valsartan, Losartan, Et Al v.
John Quick (#5063421)

ERRATA SHEET

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John Quick Date

In Re: Valsartan, Losartan, Et Al v.
John Quick (#5063421)

ACKNOWLEDGEMENT OF DEPONENT

I, John Quick, do hereby declare that I have read the foregoing transcript, I have made any corrections, additions, or changes I deemed necessary as noted above to be appended hereto, and that the same is a true, correct and complete transcript of the testimony given by me.

_____ _____
John Quick Date
*If notary is required

SUBSCRIBED AND SWORN TO BEFORE ME THIS
_____ DAY OF _____, 20___.

_____
NOTARY PUBLIC

f

n

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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In Re: Valsartan, Losartan, Et Al

John Quick (#5025079)

ACKNOWLEDGEMENT OF DEPONENT

I, John Quick, do hereby declare that I have read the foregoing transcript, I have made any corrections, additions, or changes I deemed necessary as noted above to be appended hereto, and that the same is a true, correct and complete transcript of the testimony given by me.

John Quick

2/18/22

Date

*If notary is required

SUBSCRIBED AND SWORN TO BEFORE ME THIS 18 DAY OF February, 2022.

NOTARY PUBLIC

OFFICIAL SEAL
CHRISTY MONTEMAYOR
NOTARY PUBLIC, STATE OF ILLINOIS
MY COMMISSION EXPIRES: 5/21/2025

In Re: Valsartan, Losartan, Et Al

John Quick (#5025079)

E R R A T A S H E E T

PAGE 17 LINE 7 CHANGE EMPLOYEE SHOULD BE EMPLOYER

REASON CORRECTION

PAGE 17 LINE 9 CHANGE "IN AN EMPLOY" SHOULD BE "AN EMPLOYEE"

REASON CORRECTION

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John Quick Date

In Re: Valsartan, Losartan, Et Al v.

John Quick (#5063421)

ACKNOWLEDGEMENT OF DEPONENT

I, John Quick, do hereby declare that I have read the foregoing transcript, I have made any corrections, additions, or changes I deemed necessary as noted above to be appended hereto, and that the same is a true, correct and complete transcript of the testimony given by me.

2/18/22

John Quick Date

*If notary is required

SUBSCRIBED AND SWORN TO BEFORE ME THIS 18 DAY OF February, 2022.

NOTARY PUBLIC

OFFICIAL SEAL
CHRISTY MONTEMAYOR
NOTARY PUBLIC, STATE OF ILLINOIS
MY COMMISSION EXPIRES: 5/21/2025

In Re: Valsartan, Losartan, Et Al v.

John Quick (#5063421)

ERRATA SHEET

PAGE 63 LINE 15 CHANGE ESTAGLISHED

SHOULD BE ESTABLISHMENT

REASON COURT REPORTER MISSED THIS

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John Quick Date

In Re: Valsartan, Losartan, Et Al

John Quick (#5025079)

E R R A T A S H E E T

PAGE 11 LINE N/A CHANGE Exhibit #18 in the glossary should be the Deposition of Pan Lin as correctly noted at 225:4 and on the exhibit itself.

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/s/ Nilda Isidro 3/10/22